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Guidance for the Reregistration of Pesticide Products Containing Pronamide as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS (REGISTRATION STANDARD)

CONTAINING

AS THE ACTIVE INGREDIENT

PRONAMIDE

(101701)

Case No. 0082
CAS 23950-58-5

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Section 3(g), directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task EPA has established the Registration Standards program, which reviews all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides are reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of studies required to maintain the registration of the pesticide. These may be either studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, establish reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in unreasonable adverse effects on the environment.

The scientific review, which is not contained in the Registration Standard, but is available from the National Technical Information Service, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data, the Agency is also looking for potential hazards that may be associated with the end-use (formulated) products that contain the active ingredient. If the Agency has serious concerns, the end-use products will be addressed as part of the Registration Standards program and regulatory actions, to the extent necessary to protect the public, will be proposed.

This Registration Standard contains the results of the Agency's review of products containing pronamide as the sole active ingredient. During this review, the Agency evaluated all Section 3, Section 24(c) and intrastate uses registered for pronamide.

Part I of this Standard, Regulatory Assessment, contains a description of pronamide and a summary of the Agency's assessment of the chemical. This is followed by a more thorough discussion of the data base and the resulting regulatory position.

Part II of the Registration Standard, Requirements for Registration, addresses the necessary requirements for maintaining registrations of products containing pronamide, along with the instructions for submission of the data and information to the Agency.

PART I. REGULATORY ASSESSMENT

The Agency has conducted a thorough review of the existing scientific data base on pronamide. This Part of the Standard sets forth the results of that review beginning with a description of the chemical and its uses, followed by a discussion of the risks and benefits associated with the use of pronamide. A summary of the Agency's review and position precedes the discussion.

This part concludes with the resulting regulatory position, and the rationale for these positions.

A. DESCRIPTION OF CHEMICAL

1. Description

Common Name : Pronamide

Chemical Name : 3,5-dichloro-N(1,1-dimethyl-2-propynyl) benzamide
- or -
[N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide]

Empirical Formula : $C_{12}H_{11}NOCl_2$

Trade Names : Kerb

Chemical Abstracts Service (CAS) No. : 23950-58-5

OPP (Shaughnessy) No.: 101701

2. Use Profile

Type of Pesticide : Preemergence herbicide

Pest Controlled : Annual and perennial grasses: certain broadleaf weeds

Registered Uses : Croplands; noncroplands

Predominant Use : Lettuce and alfalfa

Method of Application: Ground spray equipment; incorporation; aerially; limited hand spray

Mode of Activity : Inhibition of root and shoot growth of germinating weed seedlings

Rates of Application : 0.5 to 4.0 lbs. active ingredient per acre, depending on crop and weed problem

Formulations : 94% technical grade
50% formulation intermediate
End-use products: 50% wettable powder,
≤1% granular formulations and
≤1% granular formulations mixed with fertilizer

B. AGENCY ASSESSMENT

The Agency has conducted a thorough review of pronamide and its scientific data base. The conclusions reached and requirements to be imposed as a result of this review are discussed below.

Summary. The following summarizes the results of the Agency's assessment of pronamide.

1. Pronamide poses a limited oncogenic risk for applicators. In accordance with the Agency's proposed guidelines for carcinogen risk assessment, pronamide has been classified in Group C, Possible Human Carcinogen, pending consideration of additional data required by this Standard. This classification is based on a Medical College of Virginia (MCV) 18-month mouse oncogenicity study which indicated that hepatocellular carcinomas in male mice were present at feeding levels of 1000 and 2000 ppm. The results of this study have been confirmed and clarified by a subsequent study (MIT).

2. Pronamide poses applicator exposure and risk which can be reduced through the imposition of protective measures (protective clothing, restricted use classification, water-soluble packaging, etc.).

3. Pronamide has significant benefits that outweigh the identified risks, if protective measures are instituted.

As a result of this review, the Agency has identified missing data which are essential in completing assessment of the environmental and human risks associated with the use of pronamide. These data must be developed in order to maintain registrations of products or register new products containing pronamide. Specific data gaps are listed in Appendix A, Tables A and B.

The Agency has also determined that certain restrictions or conditions are necessary to minimize environmental and human risks. Significant requirements include continuation, from the RPAR decision (see below), of classification as a restricted use pesticide and water-soluble packaging for wettable powder end-use products, and expansion of the protective clothing requirements imposed by the RPAR decision. A complete discussion is contained in Section C, Regulatory Position and Rationale, of this part; the specific label language, when applicable, is set forth in Part II.

Background. An RPAR (Rebuttable Presumption Against Registration, or Special Review) of pronamide was initiated in 1977 on the basis of a Medical College of Virginia (MCV) 18-month mouse oncogenicity study which indicated that mice given diets containing 0, 1000, and 2000 ppm pronamide showed a treatment-related increase in hepatocellular carcinomas. The incidence of tumors was observed at 18 months in male mice only. At that time, this study provided the only evidence that pronamide is likely to be a human carcinogen. After reviewing all the available information, EPA determined that the cancer risk presumption had not been rebutted, and that the uses of pronamide posed risks of cancer to certain exposed groups. The Agency also reviewed information relating to benefits of these uses, and after considering risks in relation to benefits, determined that these risks may be reduced by modifying the terms and conditions of registration for some uses. The RPAR review was completed in 1979, and the final decision included the following:

a. Restricted use classification for 50% wettable powder end-use products.

b. Use of protective clothing during mixing and application of wettable powder formulations.

c. Implementation of water-soluble packaging for wettable powder formulations.

d. Tolerance on lettuce lowered from 2 ppm to 1 ppm to reduce dietary exposure.

Tolerance Reassessment. Tolerances have been established for residues of pronamide in or on a wide range of raw agricultural products listed in 40 CFR 180.317. These tolerances are:

Commodity	Tolerance (ppm)
Alfalfa, fresh	10.0
Alfalfa, forage	10.0
Alfalfa, hay	10.0
Apples	0.1
Artichokes	0.1
Blackberries	0.05
Blueberries	0.05
Boysenberries	0.05
Cattle, fat	0.02
Cattle, kidney	0.2
Cattle, liver	0.2
Cattle, MBYP (exc. kidney and liver)	0.02
Cattle, meat	0.02
Cherries	0.1
Clover	5.0
Crown vetch	5.0
Eggs	0.02
Endive (escarole)	2.0

Goats, fat	0.02
Goats, kidney	0.2
Goats, liver	0.2
Goats, MBYP (exc. kidney and liver)	0.02
Goats, meat	0.02
Grapes	0.1
Hogs, fat	0.02
Hogs, kidney	0.2
Hogs, liver	0.2
Hogs, MBYP (exc. kidney and liver)	0.02
Hogs, meat	0.02
Horses, fat	0.02
Horses, kidney	0.2
Horses, liver	0.2
Horses, MBYP (exc. kidney and liver)	0.02
Horses, meat	0.02
Lettuce	1.0
Milk	0.02
Nectarines	0.1
Peaches	0.1
Pears	0.1
Plums	0.1
Poultry, fat	0.02
Poultry, kidney	0.2
Poultry, liver	0.2
Poultry, MBYP (exc. kidney and liver)	0.02
Poultry, meat	0.02
Raspberries	0.05
Sainfoin	5.0
Sheep, fat	0.02
Sheep, kidney	0.2
Sheep, liver	0.2
Sheep, MBYP (exc. kidney and liver)	0.02
Sheep, meat	0.02
Trefoil	5.0

Because insufficient data are available to fully assess the established tolerances for residues of pronamide, any conclusions stated herein are subject to change.

The metabolism of pronamide in plants and animals is not adequately understood. Plant metabolites were identified in alfalfa only. The data were too variable to make definite conclusions about relative abundances of the metabolites. The data do show that if the carbonyl carbon of pronamide remains intact, all of the organoextractable terminal residues retain the 3,5-dichlorocarboxyphenyl substituent. Additional data are required depicting the distribution and metabolism of pronamide in alfalfa and lettuce. If metabolism among these two crops differs significantly, metabolism studies will be required for a representative crop in each crop group for which there is a registered use.

Residues were not characterized in tissues and milk of ruminants and no poultry data were submitted; therefore, metabolism studies utilizing ruminants and poultry are required. Residues in muscles, fat, kidney, liver, milk, and eggs must be characterized and quantified.

On receipt of the data, the tolerance definition will be examined and changed to include only those metabolites found which are of toxicological concern.

The methods of analysis of pronamide and its 3,5-dichlorobenzene-containing metabolites (calculated as pronamide) in or on plant and animal commodities are presently adequate for sample analyses and tolerance enforcement.

Sufficient data are available to ascertain the adequacy of the established tolerances for residues of pronamide in or on alfalfa forage and hay, apples, artichokes, blackberries, blueberries, cherries, clover, crown vetch, grapes, lettuce (head lettuce only), nectarines, peaches, pears, plums, raspberries, sainfoin, and trefoil.

The tolerance for residues in or on "fresh" alfalfa will be revoked. Alfalfa is available in two forms: forage, which is uncut, and hay, which is the cut alfalfa. Therefore, the term "fresh" is a misnomer and the tolerance will be revoked. Several commodity definitions and crop tolerance levels are recommended for change as set out in Section C of this Standard.

Available data support the established tolerance in head lettuce only. The preharvest interval of 55 days for residues in or on leaf lettuce is inappropriate as many varieties mature in 45 days. The registrant must either withdraw the registered use on leaf lettuce or revise the label directions so that use on leaf lettuce is practical. If the registrant proposes a change in the use directions, appropriate supportive data must be submitted.

Available data, in conjunction with data translated from lettuce, indicate that the use of pronamide on endive should result in residues no greater than 1 ppm. Therefore, the tolerance of 2 ppm should be reduced to 1 ppm for residues of pronamide in or on endive (escarole).

There are no registered uses of pronamide on boysenberries. The established tolerance will be revoked unless appropriate residue data in support of this tolerance are submitted and a registration for this use is secured.

Available data are inadequate to evaluate the established tolerances for residues in or on animal commodities.

Storage stability data for plant and animal residues must be submitted. On receipt of the plant and animal metabolism and storage stability data, the adequacy of established tolerances will be determined.

Data are needed to determine whether food/feed additive tolerances under Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) are needed for processed products of apples, alfalfa, plums, and grapes. Under the FFDCA, food additive tolerances may be issued only if it is established that the use of the food additive will be safe. Should food/feed additive tolerances be required, the Agency's review of data submitted in response to this Standard will include consideration of Section 409's criterion known as the Delaney Clause.

The provisional acceptable daily intake (PADI) for pronamide was based on the NOEL of 7.50 mg/kg in the 2-year dog study (Larson, P. and Borzelleca, J.). It should be noted that this PADI is based on systemic toxicity (non-oncogenic). The current PADI is 0.0750 mg/kg/day and the current published tolerance for pronamide has a calculated Total Maximum Residue Concentration (TMRC) of 0.0409 mg/day (1.5 kg diet). The percentage of PADI utilized is 0.91%.

Preliminary Risk Analysis. To assess the potential risks associated with pronamide, the Agency reviewed the existing data base. Based on this review, dietary risk and applicator exposure and risk have been calculated. The following is a discussion of the results of the risk assessment.

a. Review of Toxicological Studies. The toxicology data base for pronamide is not complete. The following discussion focuses on data relevant to the classification of pronamide in accordance with the EPA draft Guidelines for Carcinogen Risk Assessment.

   1. Oncogenicity Studies. The Agency has available three studies: "Eighteen month study of the carcinogenic potential of Kerb (RH-315, Pronamide) in mice," Medical College of Virginia (MCV), August 30, 1974; "Chronic toxicity study in the mouse" by Newberne et al., Massachusetts Institute of Technology (MIT), August 10,

1982; and "Toxicologic study on the effect of adding RH-315 to the diet of rats for a period of two years," (MCV), June 11, 1970;

a. MCV Mouse Study. The MCV study indicated that hybrid mice, B6C3F1, a strain with a high background incidence of liver tumors, given diets containing 0, 1000, or 2000 ppm showed a treatment-related increase in hepatocellular carcinomas. The incidence of those tumors was observed at 18 months in male mice only, and the results are summarized as follows:

Dose	Tumor Incidence
0	7/100
1000	18/100
2000	24/99

b. MIT Mouse Study. The MIT study was required by the Agency to confirm and clarify the results of the MCV study and employed males only of the same strain (B6C3F1). Of particular concern were time-to-tumor and dose-response relationships. Hence, the MIT study included interim sacrifices and a wider range of dose levels. The reported incidence of hepatocellular carcinomas was as follows:

Dietary Concentrations (ppm)	Time on diet (months)			
	6	15	18	24
0*	0/42	3/42	4/42	6/63
0**	---	0/42	2/42	5/63
20**	---	1/42	3/42	9/63
100**	---	2/42	3/42	12/63
500**	---	2/42	4/42	18/63
2500	0/42	1/42	6/41	14/61

* Control group 1.
** Control group 2, not part of the 6-month phase of the study.

The following observations were also noted in the MIT study:

(1) While dose-related carcinomas occurred late in the lifespan of test mice (at 24 months), other proliferative liver lesions were present at 15 and 18 months in the highest dose group.

(2) Approximately 60 to 100 percent (for control and test groups) of the animals examined at the end of the study exhibited proliferative liver lesions including hyperplasias, hyperplastic nodules, adenomas, and carcinomas.

(3) The number of metastases observed was not consistent with a dose-related increase.

(4) There was no dose-related effect on mortality of treated mice.

c. *Rat Study*. Pronamide was administered in the diets of rats at levels of 0, 30, 100, and 300 ppm. No toxic effects were noted in the study and only minimal effects on body weights were seen at 300 ppm. For these reasons, it was concluded that the highest dose level may have been too low and, therefore, compromised the sensitivity of the study to assess the carcinogenic potential of pronamide.

The study had several deficiencies, the test material was not adequately described and no data for diet analysis were reported. Clinical chemistry studies were not conducted and hematology and urinalysis were performed on only 5 rats/sex/group. No individual data for body weights, food consumption, clinical studies, or organ weights were reported, so the summary data could not be validated; furthermore, the methods for statistical analysis were not specified. Because of these deficiencies, EPA cannot determine whether a maximum tolerated dose was administered.

2. *Mutagenicity Studies*. The Agency has available to it four mutagenicity tests: an *in vitro* spot assay for (gene) reversion in *Salmonella typhimurium* strains TA 1530 and G46, conducted only without metabolic activation; an *in vitro* assay for mitotic recombination at only one dose in *Saccharomyces cerevisiae* D3; a host-mediated assay in mice treated subacutely (5 days) (by an unstated route of administration) employing these microbial strains as indicator organisms; and a cytogenetic assay for chromosomal aberations in bone-marrow cells of rats. Although negative results were reported for all of these assays, they are considered unacceptable by current Agency testing guidelines for adequate studies because of major deficiencies in procedure and reporting.

In the cytogenetic study, data confirming that the assay was performed at the limits of clinical or cytological toxicity were not presented. Therefore, it cannot be assessed if the dose range selected included sufficiently high levels. In addition, all aberration parameters were reported to be "0" for the negative control and for all dosages; although such results are possible, the data appear to show unusually low responses and are not consistent with historical control incidence of aberrations.

Reporting for both _in vitro_ and the subacute _in vivo_ host-mediated assays for mutagenesis was inadequate. Only general protocols were submitted, which do not clearly define what was actually done to generate the data.

The Agency is requesting a full battery of studies to evaluate the mutagenic endpoints (see Table A, Appendix A).

b. _Risk Assessment_. The Agency has classified pronamide according to the EPA draft Guidelines for Carcinogen Risk Assessment. EPA concludes that a tentative classification of pronamide as a Group C oncogen (Possible Human Carcinogen) can be made based on the effects observed in the mouse studies.

The classification of pronamide as a tentative Group C oncogen (providing limited evidence of oncogenicity) relies on two studies in the mouse which showed a dose response in heptacellular carcinoma. The MIT study was designed to confirm and clarify the MCV study which reported an increase in hepatocellular carcinoma in male mice only at 18 months on diets of 1000 and 2000 ppm pronamide. The MIT study utilized male mice only of the same strain (B6C3F1) with dietary dosages ranging from 20 to 2500 ppm pronamide and sacrifices scheduled at 6, 15, 18, and 24 months. The two studies together do not provide substantially different information than is provided by either study alone. Both studies showed a dose response in heptacellular carcinomas in a liver tumor prone strain of mice and the results of the second study clearly indicated that these dose related tumors occurred only at the end of the study, i.e., there was no decrease in the time to malignancy attributable to exposure to pronamide. These studies in mice, together with the existing rat study, constitute only limited evidence of oncogenicity, leading to a Group C classification.

Because of the absence of adequate studies in other species, or well performed short term studies, EPA is not able to make a final classification of pronamide at this time. The additional rat bioassay and short term studies required by this Standard are expected to substantially assist in determining an appropriate final classification for this pesticide.

The final RPAR decision was based in part on the results of the MCV oncogenicity study. It did not include the results of the MIT oncogenicity study which was submitted after the final RPAR decision. The results of the MIT mouse study do not significantly alter EPA's assessment of the carcinogenic risks to humans. Since pronamide has been regulated as a carcinogen in the past, the Agency has recalculated risks based on a more recently accepted statistical model.

c. Risk Estimation

Dietary Risks. Dietary risks were estimated from the published tolerances. A partial listing of dietary risks follows:

Crop	mg/kg/day	Risk (based on $Q_1^* = 1.63\times10^{-2}$)
Lettuce	.000327	10^{-6} to 10^{-5} [c][1]
Meat Products	.000069	10^{-6} [c]
Milk/ Dairy	.000143	10^{-6} [c]
Apples	.000063	10^{-6} [c]
TMRC	.0006833	10^{-5} [c]

The Theoretical Maximum Residue Contribution (TMRC) assumes that residues occur at the tolerance level on 100 percent of the crops and thus overestimates the actual dietary exposure. Using $Q_1^* = 1.63\times10^{-2}$ as the proper estimator of oncogenic potency, and the multi-stage procedure programmed to fit the data and to calculate the upper 95 percent bound on the risk associated with expected doses of the compound under study, the TMRC risk is 10^{-5}[c].

Applicator Risk. Exposure values for the major uses in mg/kg/year are:

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[1] [c] = Group C Classification (Possible Human Carcinogen), EPA's Proposed Guidelines for Carcinogen Risk Assessment.

Lettuce	Dermal	Inhalation
Loader	210	0.3
Applicator	210	Negligible

Alfalfa	Dermal	Inhalation
Loader	3	0.004
Applicator	3	Negligible

The lifetime average daily dose (LADD) was calculated from the following equation:

$$\text{LADD} = (\text{mg/kg/year}) \times (1/365) \times (35 \text{ years exposure}/70 \text{ years/lifetime})$$

Dermal absorption of 100 percent is assumed, therefore, perhaps exaggerating risks by an unknown amount.

Associated risks to lettuce and alfalfa applicators and loaders are:

	Lifetime Risk	Risk with Protective Clothing	Risk with Protective Clothing and Water Soluble Packaging
LETTUCE			
Loader	5×10^{-3} [c]1/	1×10^{-3} [c]	1×10^{-4} [c]
Applicator	5×10^{-3} [c]	1×10^{-3} [c]	1×10^{-3} [c]
ALFALFA			
Loader	6×10^{-5} [c]	1×10^{-5} [c]	1×10^{-6} [c]
Applicator	6×10^{-5} [c]	1×10^{-5} [c]	1×10^{-5} [c]

1/ [c] = Group C Classification (Possible Human Carcinogen), EPA's Proposed Guidelines for Carcinogenic Risk Assessment

Benefits and Use. Pronamide is an herbicide active on a variety of annual and perennial grasses and certain annual broadleaf weeds. It is taken in by plant roots and, therefore, must be applied to the soil and taken by water into the root zone in order to function. It is most effective against germinating seedlings but will control some weeds (e.g., annual bluegrass) after they have emerged. It is also specially effective against perennial grasses because it interferes with underground stem growth as well as root growth. Pronamide is inactivated by soil organic matter and, therefore, is not to be used on muck, peat, or other high-organic content soils.

Pronamide is sold as a wettable powder, as a granular material, or as a granular with fertilizer. The wettable powder (50 percent active ingredient (a.i.)) is used for all crop spray uses; the granular products (0.125-1.0 percent a.i.) are applied to bermudagrass turf, especially golf courses.

Pronamide is used on: lettuce (most use occurs in California and Arizona); alfalfa and other forage legumes for hay (in the Pacific northwest and upper midwest and east); alfalfa and clover seed crops (Pacific northwest); berry crops (Washington and Oregon only); ornamental bermudagrass turf, such as golf courses, playgrounds, athletic fields, and lawns (southeastern United States primarily, mostly for golf courses); woody ornamentals, nursery stock and Christmas trees (mostly north central and northwest states where quackgrass and other perennial grasses are severe); sugarbeet seed crops (Oregon only); globe artichokes in California; tree fruits and grapes (chiefly in California, some in northeastern states); and fallow land to be planted to wheat, barley or oats (Idaho, Oregon, and Washington).

Application to all sites except turf is predominantly by conventional ground spray equipment or by incorporation (on some lettuce). Often on lettuce, berries, and seed crops, it is applied in bands on or near the row so that treated acreage is about 1/2 to 1/3 of planted acreage. This reduces residues of pronamide in the soil. Granular (sometimes plus fertilizer) treatments are used on bermuda turf to carry the pronamide through the thatch to the soil surface. Aerial application is occasionally made to alfalfa (estimated at about 5 percent).

Rates of application range from 0.5 to 4 lb. per acre, depending on the crop and the weed problem. Except for spring applications to summer lettuce, August applications to fall lettuce, and late spring applications to alfalfa and clover seed crops, all applications are made in late fall or early winter, before the ground freezes. This is largely due to the need to apply pronamide when the protected crop is dormant. Because it acts as a cell division inhibitor, pronamide will control growing winter weeds while not harming the dormant crop. This practice also results in minimal residues in hay and berry crops the following summer.

There are 12 special local needs (Section 24c) registrations:

a. Aerial application to lettuce - Arizona and California;

b. Tank mix with "herbicide 273" (endothall) for use on sugarbeets - Oregon;

c. Addition of Kerb 50-W to potassium or phosphate fertilizer to provide granular application to alfalfa at the rate of 1.5 - 4 lb. a.i. per acre depending on local need Pennsylvania;

d. Tank mix with dinoseb for established alfalfa - California.

e. Mixing pronamide with potash or phosphorus fertilizers - New York and Oregon;

f. Fall application at 0.25-0.5 lb. ai/A to land prior to summer fallow before planting to winter wheat, oats, or barley - Idaho, Oregon and Washington;

g. Directed spray at 4 lb.ai/A to soil between rows of globe artichokes after winter drainage ditching operations - California; and

h. Aerial application at 3 lb. ai/A to Christmas tree plantations - Oregon.

C. REGULATORY POSITION AND RATIONALE

Based on review and evaluation of all available data and other relevant information on pronamide, the Agency has made the following determinations. Where labeling requirements are imposed, specific language in set forth in Part II.

1. If any of the risk criteria listed in Section 154.7 of Title 40 of the U.S. Code of Federal Regulations has been met or exceeded, a special review of the chemical is conducted. Pronamide has not met any of the criteria, and therefore is not being placed into the special review process at this time.

   Rationale: Although pronamide is an oncogen in male mice, EPA does not believe that pronamide meets the criterion in 40 CFR 154.7(a)(2) for initiating a special review. EPA's recently effective final special review rules provide that the Administrator may conduct a special review if a pesticide use "may pose a risk of inducing in humans an oncogenic . . . effect, which is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk . . ." (see 50 FR 49016, November 27, 1985). EPA concludes that the risk of oncogenic effects is not of sufficient concern to warrant a special review because the most recently computed risk levels are comparable to those achieved through the earlier RPAR on pronamide. Moreover, the risk levels are, in their own right, relatively low and the population of individuals the Agency knows are highly exposed, i.e, applicators, is quite limited. Finally, EPA's assessment of the risk must be tempered by the nature of the qualitative evidence indicating the carcinogenicity of pronamide. Thus, the tentative Group C classification of pronamide indicates that the Agency believes that the evidence of carcinogenic activity is limited and, therefore, open to some doubt.

2. No new significant tolerances will be considered until the Agency has received data sufficient to thoroughly evaluate pronamide. The Agency will require metabolism studies utilizing ruminants and poultry, as well as storage stability data for plant and animal residues. Residues in muscles, fat, kidney, liver, milk and eggs must be characterized and quantified. Additional data are required depicting the distribution and metabolism of pronamide in alfalfa and lettuce. If metabolism among these two crops differs significantly, metabolism studies will be required for a representative crop in each crop group for which there is a registered use.

   Rationale: The toxicological data base on pronamide is not sufficient to consider establishment of new significant tolerances. The metabolism of pronamide in plants and animals is not adequately defined. Plant metabolites were identified in alfalfa only. The data were too variable to make definite conclusions about relative abundances of metabolites. Residues were not characterized in tissues and milk of ruminants and no poultry data were submitted. Moreover, EPA has insufficient data to determine whether food additive regulations are required for certain processed foods, as provided under Section 409 of the Federal Food, Drug and Cosmetic Act.

3. Changes to the tolerance regulations under 40 CFR 180.317, will be proposed as follows:

Present Wording	New Wording
Alfalfa (fresh)	(Will be Revoked)
Boysenberries	(Will be Revoked)
Clover	Clover (forage)
Crown vetch	Crown vetch (forage)
Endive (escarole) - 2 ppm	Endive (escarole) - 1 ppm
Sainfoin	Sainfoin (forage)
Sheep meat - 0.2 ppm	Sheep meat - 0.02 ppm
Trefoil	Trefoil (forage)

Rationale: Alfalfa is used either as forage (uncut) or hay (cut); therefore, the term "fresh" is a misnomer and the tolerance should be revoked. There are no registered uses for boysenberries; unless appropriate residue data in support of this tolerance are submitted and a registration for this use secured, the tolerance should be revoked. Available data, in conjunction with data translated from lettuce, support a tolerance for endive (escarole) of 1 ppm; therefore, the tolerance should be reduced from 2 ppm to 1 ppm. The tolerance for sheep meat has been incorrectly published as 0.2 ppm; the correct tolerance is 0.02 ppm. The terminology for the remaining commodities (clover, crown vetch, sainfoin, and trefoil) should be changed to include the word "forage," which is the uncut form of these commodities and the correct definition. This change would be consistent with the crop definitions listed in the CFR.

4. The Agency will continue to classify 50% wettable powder end-use products as restricted-use pesticides, as required by the RPAR of pronamide.

Rationale: The processes of mixing and applying 50% wettable powder products pronamide pose risks to the mixers and applicators. These risks are discussed under Section B of this Part. The risks can be reduced by requiring, among other things, that 50% wettable powder pronamide products only be applied by personnel who have been made aware of these risks, i.e., certified applicators who have received instructions on the safe handling of pesticides, or those under the direct supervision of certified applicators.

5. The following data are required to assess the chronic toxicity of pronamide: chronic feeding/oncogenic study (rat); teratogenicity (rat); reproduction (2-generation); mutagenic potential; metabolism (general), and dermal penetration.

   Rationale: These data are normally required by rules in 40 CFR 158 for products with pronamide's use patterns. Most of the existing studies on pronamide do not meet the guideline standards for acceptable studies but provide only limited information on the toxicity of pronamide or are unacceptable or invalid. The Agency is, therefore, not able to thoroughly assess the chronic toxicity of pronamide.

6. The following data are required to fully assess the environmental fate of pronamide: photodegradation studies on soil and in water; aerobic soil and anaerobic aquatic metabolism studies; leaching and adsorption/desorption studies; volatility studies; field dissipation studies; and rotational crop and fish accumulation studies.

   Rationale: Except for the hydrolysis data, all the environmental data are preliminary and do not meet guideline standards for acceptable testing. These data are normally required under 40 CFR 158 and are necessary to assess the environmental fate and transport and the potential exposure to pronamide.

7. The Agency will require that labels of end-use products contain protective clothing statements. Protective clothing requirements for wettable powder formulations were required by the RPAR.

   Rationale: The potential for oncogenic risk from pronamide use is discussed in the preceding Section. This risk can be reduced significantly by requiring persons who may have significant dermal contact with the chemical to wear protective clothing, thereby reducing exposure to pronamide at a small cost.

8. The RPAR for pronamide required that wettable powder formulations be packaged in water soluble packaging. The Agency will continue this requirement.

Rationale: User exposure and risks are discussed in Section B. This packaging technology reduces mixer/loader contact with wettable powder formulations during mixing operations, thereby reducing a major source of exposure.

9. Products containing pronamide must contain general precautionary language regarding dermal and ocular contact with products containing pronamide, as required by the RPAR. In addition, labels must also contain direction about the handling of contaminated clothing.

   Rationale: Because of the risks associated with pronamide as previously discussed, the inclusion of precautionary language will emphasize the need for users to exercise caution while using pronamide and will limit risk if contact with the product occurs.

10. Restrictions are being placed on planting of crops, for which pronamide is not registered, in fields previously treated with products containing pronamide. Labels of end-use products must contain rotational crop statements.

    Rationale: The crop restriction is necessary due to the lack of adequate residue data on rotational crops. It is the policy of the Agency to impose restrictions on planting rotational crops when data are insufficient to allow an assessment of the impact of planting subsequent crops. This serves to protect the public from impermissable residues in food and feed, as well as to warn growers about how to avoid impermissible residues.

11. The Agency will continue to require that labels of granular formulations must include instruction for watering turf after application of pronamide, as originally required by the RPAR.

    Rationale: Data on particle size in the granular formulations indicate that these products do not pose the same level of risks to the applicator as wettable powders. However, thorough watering of granular formulations of pronamide after application will minimize exposure to people entering the treated area and enhance efficacy.

12. Hand-spray application of products containing pronamide will be limited to ornamentals and nursery stock. This is a continuation of an RPAR requirement.

    Rationale: Because of the method of application, hand-spray application of products containing pronamide is important in the minor uses on ornamentals and nursery stock. Because it is a minor use and because the product registered for these uses will be a restricted use pesticide requiring protective clothing which can provide hand-spray users some protection from exposure to pronamide, such uses on ornamentals and nursery stock will be permitted. Data indicate that, for other uses, mechanical application methods are used.

13. A reentry interval for currently registered uses of pronamide is not required.

Rationale: The acute toxicity for pronamide is low (Category III). Additionally, because pronamide is primarily a preemergent herbicide, exposure and the resultant risks to field workers are expected to be minimal. Therefore, no reentry interval is required.

14. While the data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing pronamide as the sole active ingredient may be sold, distributed, formulated and used in the United States, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in Tables A and B of Appendix A in order to maintain existing registrations. The Agency will issue registrations for substantially similar products. However, significant new uses will not be registered until the Agency has received data adequate to thoroughly evaluate the risks associated with pronamide use.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or inadequate (see FIFRA sections 3(c)(2)(B) and (3)(c)(7)).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated after which the Agency will determine if additional regulatory changes are necessary.

PART II. REQUIREMENTS FOR REGISTRATION

This Part of the Registration Standard discusses data, labeling revisions and packaging required to maintain existing registrations or register new products containing pronamide. It also contains the instructions for submitting the necessary data and information to the Agency.

To be covered under this Standard, products must contain pronamide as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this Part.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). Registration applicants must contact the Agency for specific instructions, including updated information on data requirements and companies whose data have been used in support of registration.

A. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard. To be covered under this Standard, products must contain pronamide as the sole active ingredient. Each technical grade or manufacturing-use formulation proposed for registration must be fully described with an appropriate certification of limits.

Acute Toxicity Limits. The Agency will consider registration of technical grade and manufacturing-use products containing pronamide, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed, as required by 40 CFR 162.10.

Use Patterns. To be registered under this Standard, technical grade or manufacturing-use products containing pronamide may be labeled for formulation into end-use products for use only on the commodities listed below. Appendix B, EPA Index to Pesticide Chemicals - Pronamide, lists all registered uses, as well as the approved maximum application rates and frequencies.

-Terrestrial, non-domestic, food uses on: alfalfa, alfalfa (seed crop), apples, globe artichokes, birdsfoot trefoil, birdsfoot trefoil (seed crop), blackberries, blueberries, cherries, clover, clover (seed crop), crown vetch, crown vetch (seed crop), endive, grapes, lettuce, nectarines, peaches, pears, plums, prunes, raspberries, sainfoin, and sainfoin (seed crop).

-Terrestrial, non-domestic, non-food uses on: bermudagrass, bermudagrass (seed crop), azalea, azalea (nursery stock), Christmas tree plantations, Douglas fir, Douglas fir (nursery stock), fir, fir (nursery stock), forsythia, forsythia (nursery stock), holly, holly (nursery stock), juniper, juniper (nursery stock), pine, pine (nursery stock), rhododendron, rhododendron (nursery stock), yew, and yew (nursery stock).

-Domestic outdoor uses on: bermudagrass, centipedegrass, St. Augustinegrass, and zoysiagrass.

B. LABELING AND PACKAGING REQUIREMENTS

All labeling changes required by this Standard must appear on all products in channels of trade within two years of issuance of this Standard. As specified packaging for wettable powder end-use products is a continuation of an existing requirement, such packaging must immediately be in use or, for new products, incorporated at the time of product introduction.

In addition to the above, the following information must appear on the labeling:

1. All Products. All products must bear appropriate labeling as specified in 40 CFR 162.10. Specific information on label requirements are contained in Appendix C.

    a. Ingredient Statement. The ingredient statement must list the active ingredient as:

        pronamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide...%

        or

        pronamide [N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide]....%

    b. Disposal Statements. Because pronamide has not been designated as an acute or toxic hazardous waste under the Resource Conservation and Recovery Act (RCRA), the following is the appropriate pesticide disposal statement for pronamide products:

        "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

    The labels of all products must bear the appropriate container disposal statement (see Appendix C-6).

2. Technical Grade/Manufacturing-Use Products

    a. Use Pattern Statements. Labeling for all technical grade and manufacturing-use pronamide products must state that they are intended for formulation into end-use herbicide products for the use patterns and sites, as set forth in the preceding section under Use Patterns. However, no use may be included on the label if the registrant fails to agree to comply with the data requirements for that use pattern, as listed in Table A and/or Table B, Appendix A, as appropriate.

b. Precautionary Statements. Labels for technical grade and manufacturing-use pesticide products must bear statements reflecting the compound's acute human toxicity, as specified in 40 CFR 162.10 (Appendix C-2), and statements pertaining to environmental hazard. Pronamide is in Toxicity Category III for dermal, inhalation, and eye irritation routes of exposure; the required precautionary statements associated with this category, and the required environmental hazard statements are set forth below.

> "CAUTION - Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with the skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

3. Statements for End-Use Products. All end-use products with outdoor agricultural uses which are applied to crops involving hand labor are required to bear precautionary label language about farmworker safety. Appendix C-7 sets forth the specific language to be used. All end-use products must also bear an environmental hazard precaution (see Appendix C-2), as set forth below along with additional required statements:

> "Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes."

> "GENERAL PRECAUTIONS: Avoid contact with eyes, skin or clothing."

> "PROTECTIVE CLOTHING: When mixing, loading or applying this product, wear midforearm waterproof gloves, long-sleeved shirts and long

pants, preferably one piece (coveralls). Hand-spray or hand-spreaders also require the use of waterproof boots or shoe coverings. Wash nondisposable gloves, boots and shoe coverings thoroughly with soap and water before removing."

"If water-soluble packaging is used, mixers and loaders are exempted from protective clothing requirements."

"Protective clothing/equipment is not needed during application if an enclosed tractor cab with filtered air supply or enclosed cockpit is used."

"Any article of clothing worn while handling product must be cleaned before reusing. Clothing should be laundered separately from household articles. Clothing which has been drenched or heavily contaminated should be disposed of in accordance with state or local regulations."

a. All 50% wettable powder end-use products must be packaged in water-soluble packaging and bear the following statements:

"RESTRICTED USE PESTICIDE: Because pronamide has produced tumors in laboratory animals, this product is for retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

"Crops other than those on which pronamide may be applied may not be planted in pronamide-treated soil."

"Hand-spray applications of pronamide may be made only to ornamentals and nursery stock."

"Dilution Instructions

"The enclosed pouches of this product are water soluble. Do not allow pouches to become wet before adding them to the spray tank. Do not handle the pouches with wet hands or gloves. Always reseal overwrap bag to protect remaining unused pouches. Do not remove water soluble pouches from overwrap except to add directly to the spray tank."

> "Add the required number of unopened pouches as determined by the dosage recommendations into the spray tank with agitation. Depending on the water temperature and the degree of agitation, the pouches should dissolve completely within approximately five minutes from the time they are added to the water."

b. All pronamide granular formulations must bear the following statement:

> "Sites treated with this product must be thoroughly watered after application."

C. SUBMISSION OF GENERIC DATA

Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. EPA has the authority under FIFRA section 3(c)(2)(B) to require registrants to submit data that will answer the Agency's questions regarding the hazard that may result from the intended use of a pesticide.

This portion of the Registration Standard is issued under the authority of FIFRA section 3(c)(2)(B). EPA has determined that additional generic data described in Table A, Appendix A, must be submitted to EPA for evaluation in order to maintain in effect the product registration(s). As required by FIFRA section 3(c)(2)(B), registrants are required to take appropriate steps to comply with this Standard.

Although section 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing-use products (basic suppliers of the active ingredient) and other registrants who do not qualify for the formulator's exemption. The formulator's exemption applies to a registrant of a product if the source of its active ingredient(s): (1) is a registered product, and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

A producer who currently does not qualify for the formulator's exemption may qualify by changing its source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the Product Manager listed in Section E of this Part within 90 days of receipt of the Registration Standard. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

Registrants are reminded that FIFRA section 6(a)(2) requires that factual information raising concerns of possible unreasonable adverse effects of a pesticide must be promptly submitted. If interim results of studies in progress show possible adverse effects, the Agency is to be notified of those interim results.

EPA may suspend the registration of products unless, within the specified time, the registrant informs EPA how it will satisfy the requirements of this Standard. Any such suspension will remain in effect until the registrant has complied with the terms of this Standard.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARD	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standard.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standard, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect humans or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Registration Standard for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company, end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the data requirements in I-A and B above, the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the data requirements in I-A and B.

1. What Generic Data Must be Submitted. Registrants may determine which generic data must be submitted by consulting Table A, Appendix A. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines 1/) or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If registrants do not wish to develop data in support of certain uses appearing in their labeling, they may delete those uses at the time they submit revised labeling.

   For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A, Appendix A. EPA may possess data on certain "typical formulations" but not others.

2. Options Available for Complying With Requirements to Submit Data. Within 90 days of receipt of this Standard, registrants must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1 (Appendix D), for each of their products. On that form, registrants must state which of the following methods they will use to comply with the requirements of this Standard:

   a. Notify EPA that they will submit the data, and either submit the existing data they believe will satisfy the requirement, or state that they will generate the data by conducting testing. If the test procedures they will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, they must enclose the protocols they will use.

OR

1/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

b. Notify EPA that they have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If they elect this option, they must notify EPA which registrant(s) are parties to the agreement.

OR

c. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data," EPA Form 8580-6 (Appendix E)[1]

OR

d. Request that EPA amend their registrations by deleting the uses for which the data are needed.

OR

e. Request voluntary cancellation of the registration(s) of the products for which the data are needed.

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[1] FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly. In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing. As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases to further this goal. Accordingly, if (1) a registrant has informed EPA of its intent to develop and submit data required by this Standard; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii); and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

3. Procedures for Requesting Changes in Testing Methodology and Extensions of Time. EPA recognizes that registrants may disagree with the Agency's conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures a registrant plans to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, the registrant must submit the protocol for Agency review prior to the initiation of the test.

   If a registrant believes it will need more time to generate the required data than is allowed by EPA's schedule, the registrant may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why the registrant believes that an extension is appropriate. While EPA considers the request, the registrant must strive to meet the deadline for submitting the required data.

4. Procedures for Requesting a Waiver of the Data Requirement. If a registrant believes that a data requirement does not (or should not) apply to its product or its uses, the registrant must provide EPA with a statement of the reason why it believes this is so. The statement must address the specific composition or use factors that lead the registrant to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not automatically extend the timeframes for developing required data, and if the waiver request is denied, the registration may be suspended if the registrant fails to submit the data.

5. Existing Stocks Provision Upon Suspension or Cancellation. EPA may permit continued sale and distribution of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of FIFRA. However, the Agency has determined that if a registration is suspended for failure to respond to a data call in request under FIFRA section 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If a registrant believes that its product will be suspended or cancelled and that an existing stocks provision should be granted, the registrant

has the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

a. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and an estimate of the time required for their sale or distribution.

b. Demonstration that such a provision would be consistent with the provisions of FIFRA.

D. SUBMISSION OF PRODUCT SPECIFIC DATA

Note: This Section applies only to 50 percent formulation intermediates (FI), not to end-use products.

A necessary first step in determining which statements must appear on a product's label is the completion and submission to EPA of product specific data listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix F), to fill gaps identified by EPA concerning the product. Under the authority of FIFRA section 3(c)(2)(B), EPA has determined that registrants must submit these data to EPA in order to reregister their product(s).

Table B, Product-Specific Data Requirements for Manufacturing Use Products, of Appendix A, lists the product specific data registrants must submit. Data that are required to be submitted are identified in that table under the column entitled "Must Data Be Submitted Under §3(c)(2)(B)." These data must be submitted not later than 6 to 12 months, as indicated on the table, after receipt of this Registration Standard.

E. INSTRUCTIONS FOR SUBMISSION

This section describes what must be submitted and the timeframes for the submissions. Addresses are provided at the end of this section.

1. Requirements

a. For Technical Grade/Manufacturing-Use Products Containing Pronamide as the Sole Active Ingredient

(1) Within 90 days from receipt of this Standard, registrants must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1 (Appendix D).

(2) Within 6 months from receipt of this Standard, registrants must submit:

(a) Confidential Statement of Formula, EPA Form 8570-4.

(b) Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this Standard and the results of the short-term data, such labeling must be submitted. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

(c) Evidence of compliance with data support requirements of FIFRA section 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for requirements.

(3) Within the times set forth in Table A, Appendix A, registrants must submit all generic data, unless they request and are granted a waiver or extension, or they are eligible for the formulator's exemption

b. For Technical Grade/Manufacturing-Use Products Containing Pronamide in Combination With Other Active Ingredients

(1) Within 90 days from receipt of this Standard, registrants must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1 (Appendix D).

(2) Within the times set forth in Table A, Appendix A, registrants must submit all generic data, unless they request and are granted a waiver or extension, or they are eligible for the formulator's exemption.

c. For End-Use Products Containing Pronamide Alone or In Combination With Other Active Ingredients

(1) Within 90 days from receipt of this Standard, registrants must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1 (Appendix D).

(2) Within 6 months from receipt of this Standard, registrants must submit:

(a) Confidential Statement of Formula, EPA Form 8570-4.

(b) Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this Standard and the results of the short-term data, such labeling should be submitted. End-use product labeling must comply specifically with the instructions in this Standard. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

(3) Within the times set forth in Table A, Appendix A, registrants must submit all generic data, unless they request and are granted a waiver or extension or they are eligible for the formulator's exemption.

d. Products Qualifying for Formulator's Exemption. Within 90 days from receipt of this Standard, registrants must submit a Formulator's Exemption Statement, Appendix G. They must also submit a current Confidential Statement of Formula or certify that the Confidential Statement of Formula on file is complete, current and accurate.

e. For Intrastate Products Containing Pronamide Either as the Sole Active Ingredient or in Combination with other Active Ingredients. These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

2. Submissions to Product Manager. Applications and other required information should be submitted to the Product Manager, Registration Division. If, for any reason, any test is delayed or terminated so that the agreed schedule cannot be met, the Product Manager must be notified as soon as it becomes clear that the schedule cannot be met.

The address for submissions to the Product Manager is:

Mr. Robert J. Taylor
Product Manager (Team 25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-1800

3. Submissions to the Office of Compliance Monitoring. If, on the FIFRA Section 3(c)(2)(B) Summary Sheet, a registrant commits to develop the data, requests a minor chemical exemption, presents arguments that a data requirement is not applicable, or submits protocols or modified protocols for Agency review, the registrant must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this Standard. Actual studies are not to be submitted.

If for any reason any test is delayed or terminated so that the agreed schedule cannot be met, the Office of Compliance Monitoring must be notified as soon as it becomes clear that the schedule cannot be met.

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

APPENDIX A

TABLE A: GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

TABLE B: PRODUCT SPECIFIC DATA REQUIREMENTS FOR PRONAMIDE (50% FI)

Data must be submitted within the timeframes listed on Tables A and B based on the issuance date of the Registration Standard.

The following symbols are used on Tables A and B. For more information, refer to 40 CFR 158, Data Requirements for Pesticide Registration.

Test Substance

TGAI = Technical Grade of the Active Ingredient
PAI = Pure Active Ingredient
PAIRA= Pure Active Ingredient, Radiolabelled
TEP = Typical End-Use Product
EP = End-Use Product

Guideline Status

R = Required
CR = Conditionally Required

Use Patterns

A = Terrestrial, Food Crop
B = Terrestrial, Non-Food
C = Aquatic, Food Crop
D = Aquatic, Non-Food
E = Greenhouse, Food Crop
F = Greenhouse, Non-Food
G = Forestry
H = Domestic Outdoor
I = Indoor

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	R	☐	☒		
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	☒	☐	1	6 months
61-3 - Discussion of Formation of Impurities	TGAI	R	☒	☐	2	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	☒	☐	3	12 months
62-2 - Certification of Ingredient Limits	MP	R	☒	☐	4, 5	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	R	☒	☐	4, 6	12 months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	☐	☒		
63-3 - Physical State	TGAI	R	☐	☒		
63-4 - Odor	TGAI	R	☒	☐	7	6 months

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics						
63-5 - Melting Point	TGAI	R	☐	☒		
63-6 - Boiling Point	TGAI	R	☐	☒		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☐	☒		
63-8 - Solubility	TGAI or PAI	R	☐	☒		
63-9 - Vapor Pressure	PAI	R	☐	☒		
63-10 - Dissociation constant	PAI	R	☒	☐		6 months
63-11 - Octanol/water partition coefficient	PAI	CR	☒	☐	8	6 months
63-12 - pH	TGAI	CR	☒	☐		6 months
63-13 - Stability	TGAI	R	☒	☐	9	6 months
63-17 - Storage Stability	MP	R	☐	☒		
Other Requirements						
64-1 - Submittal of Samples	TGAI, PAI	CR	☐	☒		

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

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§158.120 Product Chemistry (Continued)

1/ The registrant must submit details of the manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions. the duration of each step of the process, purification procedures and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

2/ A discussion of each impurity believed to be present at ≥0.1% based on knowledge of the beginning materials, all possible chemical reactions and any contamination must be provided.

3/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present for which a certified limit is required (greater than 0.1%).

4/ Since no MP's are registered, tests must be conducted on the TGAI.

5/ Upper and lower limits for pronamide and upper limits for each impurity present at 0.1% must be provided and certified.

6/ The registrant must submit quantitative methods to detect pronamide and all impurities and inerts for which a certified limit is required. Each method must be accompanied by validation studies of the precision and accuracy of the method.

7/ The submitted description of the odor ("mild, inoffensive") is not sufficiently descriptive: a new description must be submitted.

8/ Data on the octanol/water partition coefficient have been submitted, but were not reviewed in time for inclusion in the Registration Standard.

9/ Since no information was provided as to the sensitivity to metal ions and metal, stability at evalated temperatures, and sensitivity to sunlight, additional data are required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Time Frames For Data Submission
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
Plants	PAIRA	Partially	00107953 00107958 00107957 GS0082-01	Yes[1] - 18 months[2]
Livestock	PAIRA and Plant Metabolites	Partially	00107954 00107958	Yes[3] - 18 months
171-4 - Residue Analytical Method				
Plant Residues	TGAI and Metabolites	Yes	00035563 00107958 00035565 00107959 00035566 00107960 00070933 00107961 00070934 00107965 00074523 00107967 00077215 00125382 00107957	No
Animal Residues	TGAI and Metabolites	Yes		
171-4 Storage Stability	TEP	No		Yes[4]
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Crop Group 1 - Leafy Vegetables[5]				
o Crop 1 - Endive -- Crop Field Trials	TEP	Yes	00107957	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Time Frames For Data Submission
§158.125 Residue Chemistry (Continued)				
171-4 - Magnitude of the Residue - Residue Studies (Continued)				
o Crop 2 - Lettuce -- Crop Field Trials	TEP	Yes	00070933 00107957 00107958	No6/
o Crop 3 - Rhubarb -- Crop Field Trials	TEP	No	-	No7/
Crop Group 2 - Pome Fruits Group8/				
o Crop 1 - Apples -- Crop Field Trials	TEP	Partially	00035563 00074523	Yes9/ - 18 months2/
o Crop 2 - Pears -- Crop Field Trials	TEP	Yes	00035564 00074523	No
Crop Group 3 - Stone Fruits Group10/				
o Crop 1 - Cherries -- Crop Field Trials	TEP	Yes	00074523	No
o Crop 2 - Nectarines -- Crop Field Trials	TEP	Yes	00074523	No

TABLE A

GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission
§158.125 Residue Chemistry (Continued)				
171-4 - Magnitude of the Residue - Residue Studies (Continued)				
o Crop 3 - Peaches -- Crop Field Trials	TEP	Yes	00035565 00074523	No
o Crop 4 - Plums -- Crop Field Trials	TEP	Partially	00074523	Yes[11] - 18 months[2]
Crop Group 4 - Small Fruits and Berries Group[12]				
o Crop 1 - Blackberries -- Crop Field Trials	TEP	Yes	00107960	No
o Crop 2 - Blueberries -- Crop Field Trials	TEP	Yes	00035566	No
o Crop 3 - Boysenberries -- Crop Field Trials	TEP	No	-	Yes[13] - 18 months[2]
o Crop 4 - Grapes -- Crop Field Trials	TEP	Partially	00074523	Yes[14] - 18 months[2]
o Crop 5 - Raspberries -- Crop Field Trials	TEP	Yes	00107960	No
Crop Group 5 - Grass Forage, Fodder and Hay Group[15]				
o Crop 1 - Grass forage, fodder and hay -- Crop Field Trials	TEP	No	-	No[7]

TABLE A

GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission
§158.125 Residue Chemistry (Continued)				
171-4 - Magnitude of the Residue - Residue Studies (Continued)				
Crop Group 6 - Non-Grass Animal Feeds Group [16]/				
o Crop 1 - Alfalfa forage and hay -- Crop Field Trials	TEP	Partial	00033380 00107958 00107965 00107967	Yes[17]/ - 18 months[2]/
o Crop 2 - Clover forage and hay -- Crop Field Trials	TEP	Yes	00107958	No[18]/
o Crop 3 - Crown Vetch Forage and Hay -- Crop Field Trials	TEP	Yes	00107965	No[19]/
o Crop 4 - Sainfoin Forage and Hay -- Crop Field Trials	TEP	Yes	00107965	No[20]/
o Crop 5 - Trefoil Forage and Hay -- Crop Field Trials	TEP	Yes	00107965	No[21]/
Miscellaneous Commodities				
o Crop 1 - Artichokes -- Crop Field Trials	TEP	Yes	00077215 00125382	No
o Crop 2 - Safflower Seed -- Crop Field Trials	TEP	No	-	No[7]/

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission
§158.125 Residue Chemistry (Continued)				
171-4 - Magnitude of the Residue - Residue Studies (Continued)				
Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	No	-	No22/

1/ Registrants must submit data depicting the distribution and metabolism of ring-labeled [^{14}C] pronamide in: (1) alfalfa harvested 25, 45, and 120 days after a post-emergent broadcast application using a rate sufficient to permit complete characterization of all ^{14}C-residues, and (ii) lettuce harvested 55 days after a post-emergent broadcast application preceded by a preplant or preemergent broadcast application at rates sufficiently high to permit complete characterization of ^{14}C-residues. If bound residues (i.e., residues not extracted by the solvent(s) used) represent a significant proportion of the terminal residue, analyses must include hydrolysis and reextraction of plant residues to determine the nature of conjugated residues of pronamide. If metabolism among these two representative crops is found to differ significantly, metabolism will be required for a representative crop in each crop group for which there is a registered use for pronamide. Representative samples from the above-described tests must also be analyzed by the enforcement methods to ascertain that all metabolites of concern are detected.

2/ Registrants are provided 18 months to submit data commencing with the first planting season after issuance of the Standard, consistent with PR Notice 85-5. Data are due no later than January 1988.

3/ Registrants must submit metabolism studies utilizing ruminants and poultry. Animals must be dosed for 3 days with ring-labeled [^{14}C] pronamide at a concentration in the total diet which will result in sufficient residues in the tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (milk and eggs must be collected twice daily). ^{14}C-Residues must be characterized and quantified in muscle, fat, kidney, liver, milk, and eggs. Samples from the studies should also be analyzed by the enforcement methods to ascertain that all metabolites of concern are determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

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§158.125 Residue Chemistry (Continued)

4/ The storage intervals and conditions of storage of samples used to support all established tolerances for residues in or on plant commodities must be submitted. These data must be accompanied by data depicting the percent decline in residues of pronamide at the times and under the conditions specified. After receipt of these data, the adequacy of the tolerances will be evaluated. All residue data requested in this Standard must be accompanied by data regarding the storage length and conditions of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified. Since the nature of the residue in plants and animals has not been adequately described, if the requested metabolism data reveal additional metabolites of toxicological concern, additional data depicting the stability of such metabolites in storage will be required.

5/ A crop group tolerance is not appropriate unless a use is proposed, and residue data submitted, for celery and spinach, representative commodities. In addition, additional data are required for lettuce (leaf lettuce only).

6/ The available data provide adequate support for the established tolerance covering residues of pronamide in or on head lettuce only. The registrant must either withdraw the registered use on leaf lettuce or revise the label directions to delete the post-emergent application method. If the registrant proposes a change in the use directions, appropriate supportive residue data must be submitted.

7/ No conclusions regarding the adequacy of this proposed tolerance will be made at this time, because the data submitted in support of the tolerance are under review.

8/ A crop group tolerance is not appropriate unless data are submitted depicting residues of pronamide and its metabolites in or on mature pears harvested from trees which received a single directed spray application of the 50 percent wettable powder at 4 lb. ai/A the previous fall following harvest. Tests would have to be conducted in California and Washington, which produce >70% of U.S. pears.

9/ The registrants must submit data indicating the level of residues in wet pomace, dry pomace, and juice processed from apples bearing measurable weathered residues. Use of exaggerated application rates may be necessary to obtain measurable residues in the raw commodity. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

10/ Adequate data are available to support the established tolerances for the representative commodities, cherries, peaches, and plums/fresh prunes, all at 0.1 ppm. Since registered usage on these crops is identical, it is recommended that a crop group tolerance of 0.1 ppm be proposed.

11/ The registrants must submit residue data from dried prunes processed from fresh prunes bearing measurable weathered residues. Exaggerated rates may be necessary to achieve measurable initial residues in fresh prunes which are to be processed into dried prunes. If concentration occurs, an appropriate food additive tolerance must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

§158.125 Residue Chemistry (Continued)

12/ A crop group tolerance is not appropriate unless residue data and proposed uses are submitted for cranberries and strawberries, representative commodities.

13/ There are no registered uses of pronamide on boysenberries. The tolerance for residues of pronamide in or on boysenberries will be cancelled unless the registrant proposes a use and submits appropriate residue data in support of the established tolerance, or if the proposed use directions and limitations are identical to those for blackberries, the registrant may use translatable data from blackberries and raspberries in support of the established tolerance.

14/ The registrants must submit data indicating residues of pronamide in raisins, wet pomace, dry pomace, raisin waste, and juice processed from grapes bearing measurable weathered residues. Use of exaggerated application rates may be necessary to obtain measurable residues in the raw commodity. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

15/ Data submitted in support of a crop group tolerance are pending.

16/ Based on the available data for the representative raw agricultural commodities alfalfa and clover, it is recommended that a crop group tolerance of 10 ppm be proposed for the residues of pronamide and its metabolites in or on non-grass animal feed forage and hay. Tolerances for alfalfa (10 ppm) and clover (5 ppm) do not vary by more than a factor of 5 from the tolerances for any crop in the group. These data satisfy the requirements for crop group tolerance establishment.

17/ The registrant must submit data depicting residues in or on alfalfa seed from alfalfa bearing measurable weathered residues. An appropriate tolerance must be proposed if residues are higher in the seed than in the raw agricultural commodity.

18/ Sufficient data are available to support the tolerance for the combined residues of pronamide and its metabolites in or on clover. The commodity definition "clover" in 40 CFR 180.317 will be changed to "clover (forage)," the presently accepted term for this commodity. While data have been submitted for clover hay, a raw agricultural commodity of clover, a corresponding tolerance has not been proposed or established. The registrant should propose a tolerance for residues of pronamide and its metabolites in or on clover hay; a level of 5 ppm is recommended. In lieu of such a proposal, the registrant may propose a crop group tolerance (see footnote 16).

19/ Sufficient data are available to support the tolerance for the combined residues of pronamide and its metabolites in or on crown vetch forage. The commodity definition "crown vetch" in 40 CFR 180.317 will be changed to "crown vetch forage," the presently accepted term for this commodity. No data have been submitted for crown vetch hay, a raw agricultural commodity of crown vetch, nor has a corresponding tolerance been proposed. The registrant should submit a proposal for a tolerance for residues in or on crown vetch hay; a level of 5 ppm is recommended, based on translatable clover hay data. In lieu of such a proposal, the registrant may propose a crop group tolerance (see footnote 16).

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

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§158.125 Residue Chemistry (Continued)

20/ Sufficient data are available to support the tolerance for the combined residues of pronamide and its metabolites in or on sainfoin. The commodity definition "sainfoin" will be changed to "sainfoin forage," the presently accepted term for this commodity. While data have been submitted for residues in or on sainfoin hay, a raw agricultural commodity of sainfoin, a corresponding tolerance has not been proposed. The registrant should propose a tolerance for residues of pronamide and its metabolites in or on sainfoin hay; a level of 5 ppm is recommended, based on translation from clover hay. In lieu of such a proposal, a crop group tolerance can be proposed (see footnote 16).

21/ Sufficient data are available to support the tolerance for the combined residues of pronamide and its metabolites in or on trefoil. The commodity definition "trefoil" will be changed to "trefoil forage," the presently accepted term for this commodity. No data have been submitted for trefoil hay, a raw agricultural commodity of trefoil nor has a corresponding tolerance been proposed. The registrant should submit a proposal for a tolerance for residues in or on trefoil hay; a level of 5 ppm is recommended, based on translatable clover hay data. In lieu of such a proposal, the registrant may propose a crop group tolerance (see footnote 16).

22/ The nature of the residue in animals has not been adequately described. On receipt of the requested animal metabolism data, the appropriate nature of tolerances for residues in animal products will be determined and the adequacy of the available data on the magnitude of residues in animal products will also be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission
§158.130 Environmental Fate					
Degradation Studies-Lab					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,H	Yes	00107980	No
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No	-	Yes - 9 months[1]/
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes[2]/
161-4 - In Air	TGAI or PAIRA	N/A[3]/			
Metabolism Studies-Lab					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,H	No	-	Yes - 27 months[1]/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes[4]/
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A[3]/			
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A[3]/			
Mobility Studies					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,H	No	-	Yes[5]/ - 12 months[1]

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GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission
§158.130 Environmental Fate (Continued)					
Mobility Studies (Continued)					
163-2 - Volatility (Lab)	TEP	A	No	-	Yes - 12 months
163-3 - Volatility (Field)	TEP	A	No	-	Reserved[6]/
Dissipation Studies-Field					
164-1 - Soil	TEP	A,B,H	No	-	Yes - 27 months[1]/
164-2 - Aquatic (Sediment)	TEP	N/A[3]/			
164-3 - Forestry	TEP	N/A[3]/			
164-4 - Combination and Tank Mixes		N/A[3]/			
164-5 - Soil, Long-term	TEP	A	No	-	Reserved[7]/
Accumulation Studies					
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes - 39 months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved[8]/

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission
§158.130 Environmental Fate (Continued)					
Accumulation Studies (Continued)					
165-3 - Irrigated Crops	TEP	N/A3/			
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	Yes - 12 months
165-5 - In Aquatic Non-Target Organisms	TEP	N/A3/			

1/ Data for this requirement submitted in response to the May 1984 Special Data Call In Notice for Ground Water Data have been determined to be invalid. Therefore, new or additional data must be submitted. Additional data to supplement the previously submitted studies include raw data to support conclusions; material balance; incubation temperature and pH; in addition, the solutions were not buffered; the test substance was not identified sufficiently; the light source was not specified; and the test was for less than 30 days.

2/ Data to fill this requirement have been submitted but have not been reviewed.

3/ Not required for this chemical.

4/ Data are due in June 1986, in accordance with the May 1984 Special Data Call In Notice for Ground Water Data.

5/ Adsorption/desorption data are required for Domestic Outdoor use patterns. For the other use patterns, either adsorption/desorption or any of the other methods (e.g. TLC, column) will be acceptable.

6/ Data will be required unless the results of the laboratory volatility study indicate these data are unnecessary.

7/ Data will be required unless the results of the field dissipation study indicate these data are unnecessary.

8/ Data will be required unless the results of the confined crops study indicate these data are unnecessary.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.135 Toxicology					
Acute Testing					
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,H	Yes	00083663	No
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,H	Yes	00083663	No
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,H	Yes	00083663	No
81-4 - Primary Eye Irritation	MP	A,B,H	Yes	00083663	No
81-5 - Primary Dermal Irritation	MP	A,B,H	Yes	00126574	No
81-6 - Dermal Sensitization	MP	A,B,H	Yes	00062605	No
81-7 - Delayed Neurotoxicity - Hen	TGAI	N/A1/			
Subchronic Testing					
82-1 - 90-Day Feeding - Rodent, and	TGAI	N/A2/			
- Non-rodent (Dog)					

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GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.135 Toxicology (Continued)					
Subchronic Testing (Continued)					
82-2 - 21-Day Dermal - Rabbit	TGAI	N/A[2]			
82-3 - 90-Day Dermal - Rabbit	TGAI	N/A[2]			
82-4 - 90-Day Inhalation: - Rat	TGAI	N/A[2]			
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	N/A[1]			
-Mammal					
Chronic Testing					
83-1 - Chronic Toxicity - 2 species:	TGAI				
- Rodent, and		A,B,H	No	-	Yes - 50 months
- Non-rodent (Dog)		A,B,H	Partially	00107949	No
83-2 - Oncogenicity - 2 species:	TGAI				
- Rat (preferred), and		A,B,H	No	-	Yes - 50 months
- Mouse (preferred)		A,B,H	Yes	00107968	No

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GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.135 Toxicology (Continued)					
Chronic Testing (Continued)					
83-3 - Teratogenicity - 2 species:	TGAI				
- Rat		A,B,H	No	-	Yes - 15 months3/
- Rabbit		A,B,H	Yes	00148064 00148065	No
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,H	No	-	Yes - 39 months
Mutagenicity Testing					
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,H	No	-	Yes - 9 months
84-2 - Structural Chromosomal Aberration	TGAI	A,B,H	No	-	Yes - 12 months
84-4 - Other Genotoxic Effects	TGAI	A,B,H	No	-	Yes - 12 months
Special Testing					
85-1 - General Metabolism	PAI or PAIRA	A,B,H	No	-	Yes - 24 months
85-2 - Dermal Penetration	Choice	A,B,H	No		Yes - 12 months
86-1 - Domestic Animal Safety	Choice	N/A2/			

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

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§158.135 Toxicology (Continued)

1/ Pronamide is neither an organophosphate, nor an analog of a neurotoxic compound, hence, no delayed neurotoxicity study is required.

2/ Not applicable to exposure conditions.

3/ Data for this requirement submitted in response to the October 1982 Data Call In Notice have been determined to be invalid. Therefore, new data must be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.145 Wildlife and Aquatic Organisms					
Avian and Mammalian Testing					
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,H	Yes	00107997	No
71-2 - Avian Subacute Dietary Toxicity -Upland Game Bird, and -Waterfowl	TGAI	A,B,H	Yes	00107993 00107994 00108002 00108003	No
71-3 - Wild Mammal Toxicity	TGAI	N/A[1]			
71-4 - Avian Reproduction	TGAI	N/A[2]			
71-5 - Simulated Field and Actual Testing - Mammals and Birds	TEP	N/A[2]			
Aquatic Organism Testing					
72-1 - Freshwater Fish Toxicity					
- Coldwater Fish Species	TGAI	A,B,H	Yes	00107996	No
- Warmwater Fish Species	TGAI	A,B,H	Yes	00107196 00107996	No
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,H	Yes	00098313	No

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GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.145 Wildlife and Aquatic Organisms (Continued)					
Aquatic Organism Testing (Continued)					
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	N/A2/			
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	N/A2/			
72-5 - Fish - Life-Cycle	TGAI	N/A2/			
72-6 - Aquatic Organism Accumulation	TGAI, PAI or degradation product	N/A1/			
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	N/A2/			

1/ Data not normally required for these uses.
2/ Data not required due to low toxicity and low expected ecological effect.

TABLE A
GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.155 Nontarget Insect					
Nontarget Insect Testing - Pollinators					
141-1 - Honey bee acute contact toxicity	TGAI	A,B,H	Yes	00028772	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	N/A1/			
141-4 - Honey bee subacute feeding study					Reserved2/
141-5 - Field testing for pollinators	TEP	N/A3/			
Nontarget Insect Testing - Aquatic Insects					
142-1 - Acute toxicity to aquatic insects					Reserved4/
142-1 - Aquatic insect life-cycle study					Reserved4/
142-3 - Simulated or actual field testing for aquatic insects					Reserved4/

TABLE A

GENERIC DATA REQUIREMENTS FOR PRONAMIDE (94% Technical)

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.155 Nontarget Insect (Continued)					
143-1 - Nontarget Insect Testing - Predators thru and Parasites 143-3					Reserved[4/]

1/ Because data from the acute contact tests indicate low toxicity, data on residual toxicity are not required.
2/ This requirement is reserved pending development of test methodology.
3/ Data reviewed to date do not indicate any need for a field study.
4/ This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PRONAMIDE (50% FI)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	☐	☒		
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	☒	☐	1	6 months
61-3 - Discussion of Formation of Impurities	MP	R	☒	☐	2	12 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	☒	☐	3	6 months
62-2 - Certification of Limits	MP	R	☒	☐	4	6 months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	☒	☐	5	6 months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	☐	☒		
63-2 - Physical State	MP	R	☐	☒		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PRONAMIDE (50% FI)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-4 - Odor	MP	R	☐	☒		
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☐	☒		
63-12 - pH	MP	CR	☐	☒		
63-14 - Oxidizing or Reducing Action	MP	CR	☐	☒		
63-15 - Flammability	MP	CR	☐	☒		
63-16 - Explodability	MP	R	☐	☒		
63-17 - Storage Stability	MP	R	☐	☒		
63-18 - Viscosity	MP	CR	☐	☒		
63-19 - Miscibility	MP	CR	☐	☒		
63-20 - Corrosion Characteristics	MP	R	☐	☒		
Other Requirements						
64-1 - Submittal of samples	MP	CR	☐	☒		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PRONAMIDE (50% FI)

Product Chemistry §158.120 (Continued)

1/ The registrant must submit details of the manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

2/ A discussion of each impurity believed to be present at $\geq$0.1% based on knowledge of the beginning materials, all possible chemical reactions and any contamination must be submitted.

3/ Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present for which a certified limit is required (greater than 0.1%).

4/ Upper and lower limits for pronamide and for each intentionally added inert, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified.

5/ The registrant must submit quantitative methods to determine pronamide and all impurties and inerts for which a certified limit is required (greater than 0.1%). Each method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PRONAMIDE (50% FI)

Data Requirements	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.135 Toxicology				
Acute Testing				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00085504 00085505 00133112	No
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00085505 00085511	No
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	00133112	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00085505 00133112	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00085505 00133112	No
81-6 - Dermal Sensitization - Guinea Pig	MP	No	-	Yes - 9 months

APPENDIX B

EPA INDEX TO PESTICIDE CHEMICALS - PRONAMIDE

01701

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

TYPE PESTICIDE: Herbicide

FORMULATIONS:
FI (50%)
G (0.32%, 0.33%, 0.4%, 0.9%, 1%)
WP (50%)

GENERAL WARNINGS AND LIMITATIONS: A selective, soil active herbicide used for the preemergence or early postemergence control of many broadleaf weeds and grasses. Moisture in the form of rain, melting snow, or irrigation is necessary to move the chemical into the root zone of germinating weeds. Apply in 20 to 50 gallons of water per acre by ground, or in 5 to 10 gallons by air. Aerial applications should be made only where specified. Use a low pressure sprayer for ground applications. Pronamide is most effective in coarse to medium textured soils with less than 4 percent organic matter content. Where a dosage range is given, use the lower dosage on coarse and medium textured soils and the higher dosage on fine soils. For best results, apply to a clean soil surface, free of decaying crop or weed debris. Pronamide is more effective in cool weather; degradation of the chemical occurs on the soil surface in warm weather. If application is made when air temperature is above 85 F (29.4 C), chemical should be incorporated to a shallow depth, or watered into the soil as soon as possible after application. When a band application is made, reduce dosage in proportion to band area actually treated. According to Position Document/4 on pronamide, products with more than 1 percent a.i. should be classified for restricted use.

Livestock Tolerances:

Cattle (fat, meat and mbyp except kidney and liver)	0.02 ppm
Cattle (kidney and liver)	0.2 ppm
Eggs	0.02 ppm
Goats (fat, meat and mbyp except kidney and liver)	0.02 ppm
Goats (kidney and liver)	0.2 ppm
Hogs (fat, meat and mbyp except kidney and liver)	0.02 ppm
Hogs (kidney and liver)	0.2 ppm
Horses (fat, meat and mbyp except kidney and liver)	0.02 ppm
Horses (kidney and liver)	0.2 ppm
Milk	0.02 ppm
Poultry (fat, meat and mbyp except kidney and liver)	0.02 ppm
Poultry (kidney and liver)	0.2 ppm
Sheep (fat, meat and mbyp except kidney and liver)	0.02 ppm
Sheep (kidney and liver)	0.2 ppm

*Pronamide
Kerb
N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

DEFINITION OF TERMS:
a.i. = active ingredient
lb = pounds
mbyp = meat byproducts

TIME REQUIRED FOR CONTROL: Three to 5 weeks are required to control annual bluegrass.

MODE OF ACTION: Pronamide affects the meristematic tissues of roots resulting in cell enlargement, necrosis, and an increase in nuclear volume in the treated apices. Premature differentiation and maturation of root tissues with eventual vacuolation of the apical meristematic cells completely inhibits root growth.

BROADLEAF WEEDS CONTROLLED:

PEWAIBE	Black nightshade	(b)
PFGAEBF	Burning nettle	(b)
PADABBA	Carpetweed	(b)
PAZAOBB	Common chickweed	(a)
PBDAEBA	Common lambsquarters	(b)
PEDADBA	Common purslane	(b)
PBGADAA	Dodder	(b)
PEWAIBG	Hairy nightshade	(b)
PCOAFBA	Henbit	(b)
PDAAHBD	Little mallow	(b)
PBKBDBB	London rocket	(b)
PAZADBC	Mouseear chickweed	(a)
PBDAEBI	Nettleleaf goosefoot	(b)
PEAAGBM	Pale smartweed	(b)
PEAAGBD	Prostrate knotweed	(b)
PCQBYBH	Red clover	(b)
PBKAHBA	Shepherdspurse	(b)
PBGAFBL	Tall morningglory	(b)
PEWAKBA	Tomato (volunteer)	(b)
PBKAFBE	Wild mustard	(b)
PBKBABA	Wild radish	(b)

(a) Preemergence and early postemergence control.
(b) Preemergence control only.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

GRASSES AND OTHER MONOCOTS CONTROLLED:

CABMBE	Alta fescue	(a)
CACKBA	Annual bluegrass	
CABSAA	Barley (volunteer)	(a)
CABHBB	Barnyardgrass	(b)
CAADAA	Bentgrass	(a)
CACKAA	Bluegrass	
CACHBB	Canarygrass	(b)
CAATBM	Downy brome	(a)
CACEBD	Fall panicum	(b)
CABSBC	Foxtail barley	(a)
CABIBA	Goosegrass	(b)
CABZBA	Italian ryegrass	(a)
CACKBD	Kentucky bluegrass	(a)
CABFBF	Large crabgrass	(b)
CABKAA	Lovegrass	(b)
CAAOAA	Oat	(a)
CABBBA	Orchardgrass	(a)
CABZBC	Perennial ryegrass	(a)
CAACBA	Quackgrass	(a)
CACTAA	Rye (volunteer)	(a)
CABRBA	Velvetgrass	(a)
CADFBA	Wheat (volunteer)	(a)
CAAOBB	Wild oat	(a)
CACUBD	Yellow foxtail	(b)

(a) Preemergence and early postemergence control.
(b) Preemergence control only.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Crop rotation instructions:

1. When rotation crops other than artichoke, lettuce, endive or escarole are to be planted in treated areas, knock down the beds and cross-disc the field before planting.
2. When pronamide treatment is to be followed by a rotation crop within 6 months of application, make bed-top or band applications.
3. When pronamide treatment of 0.5 lb a.i./A or higher will be followed by small grains or grasses within 1 year, treatment should be limited to band or bed-top application.
4. a. When pronamide treatment is made at 0.5 lb a.i./A, artichoke, lettuce, endive and escarole may be planted immediately; beans, corn, cotton, sorghum, carrots, celery, broccoli, cabbage, cauliflower, cucurbits, spinach, sugarbeets, onions and tomatoes may be planted after 3 months; wheat, barley, oats and grasses may be planted after 6 months.
   b. When pronamide treatment is made at 1 lb a.i./A, artichoke, lettuce, endive and escarole may be planted immediately; beans, corn, cotton, sorghum, carrots and celery may be planted after 3 months; broccoli, cabbage, cauliflower, cucurbits, spinach, sugarbeets, onions and tomatoes may be planted after 4 months; wheat, barley, oats and grasses may be planted after 9 months.
   c. When pronamide treatment is made at 1.5 lb a.i./A, artichoke, lettuce, endive and escarole may be planted immediately; beans, corn, cotton, sorghum, carrots and celery may be planted after 4 months; broccoli, cabbage, cauliflower, cucurbits, spinach, sugarbeets, onions, and tomatoes may be planted after 6 months; wheat, barley, oats and grasses may be planted after 9 months.
   d. When pronamide treatment is made at 2 lb a.i./A, artichoke, lettuce, endive and escarole may be planted immediately; beans, corn, cotton, sorghum, carrots and celery may be planted after 5 months; broccoli, cabbage, cauliflower, cucurbits, spinach, sugarbeets, onions and tomatoes may be planted after 7 months; wheat, barley, oats and grasses may be planted after 12 months.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
23001AA 23001BA	Alfalfa	N.F. (seed) 10 ppm (fresh alfalfa, forage and hay) Do not graze treated fields or harvest for forage or hay for these intervals: 25 days in areas West of Mississippi River, when the dosage is up to 1.5 lb a.i./A; 45 days in areas West of Mississippi River, when the dosage is 1.5 to 2 lb a.i./A; 120 days in areas East of Mississippi River, when the dosage is up to 2 lb a.i./A. Do not use more than 2 lb a.i./A per crop season. General Information: If fall treated alfalfa should be killed in winter, do not plant small grains or grass crops in the same field in the spring.
	0.5-2 (50% WP)	Postemergence. Broadcast. Apply to established alfalfa during fall or winter after the last cutting when temperatures are cool. Apply to fall seeded alfalfa after the trifoliate stage. Application to spring seeded alfalfa should be made the following fall or early winter.
	0.75-1 (50% WP)	Postemergence. Broadcast. Spring application for control of downy brome. Apply just before or just after germination of downy brome. Also refer to Alfalfa (seed crop) for more information pertinent only to that site.
23001BA	Alfalfa (seed crop)	N.F. (seed) 10 ppm (fresh alfalfa, forage and hay)
	1.5-2 (50% WP)	Use limited to CA, ID, NV, OR, UT, and WA. Broadcast. Spring application for preemergence control of dodder in established alfalfa. Incorporate lightly at the time of application and furrow irrigate within 7 days.
	1.5 (50% WP)	Use limited to CA, ID, NV, OR, UT, and WA. Broadcast. Spring application for preemergence control of dodder in established alfalfa. Flood the field within 1 to 3 days after application. Also refer to Alfalfa for additional use and dose information.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/04001AA	Apple	0.1 ppm Do not graze or feed treated foliage to livestock. Do not use more than 4 lb a.i./A per season.
/05002AA	Cherry	
/01014AA	Grapes	
/05003AA	Nectarine	
/05004AA	Peach	
/04003AA	Pear	
/05005AA	Plum	
/05006AA	Prune	
	1-4 (50% WP)	Directed spray. Broadcast or band. Make a single application in the fall after fruit is harvested, but prior to leaf-drop and before the soil freezes. Application may be made to bearing or nonbearing trees and vines. Use only on established plantings. Do not use on seedling trees or vines less than 1 year old, or on fall transplanted stock within 1 year of transplanting or on spring transplanted stock within 6 months of transplanting.
/13018AA	Artichoke, Globe	0.1 ppm Sixty day preharvest interval. General Information: Apply only once per crop season. Rainfall or overhead sprinkler irrigation is essential within 1 to 3 days after application to activate the chemical. When dosage exceeds 2 lb a.i./A, do not plant anything except artichokes for 18 months. For dosages up to 2 lb a.i./A, follow crop rotation instructions given under General Warnings and Limitations for Agricultural Crops.
	2 (50% WP)	Posttransplant. Band application over the row. Apply after transplanting the crowns but before new shoots have 3 to 4 leaves. Apply preemergent to the weeds. Do not use on peat or muck soils.
	2-4 (50% WP)	Postemergence. Band application over the row. Apply to established crop preemergent to the weeds and before artichoke leaves are more than 16 inches long. Use the higher dosage on fine soils.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
23011AA	Birdsfoot Trefoil	5.0 ppm
23011BA	Birdsfoot Trefoil (seed crop)	N.F. (seed) Do not graze treated fields or harvest for forage for 120 days. Do not use more than 2 lb a.i./A per crop season.
23003AA	Clover	
23003BA	Clover (seed crop)	
23024AA	Crown Vetch	
23024BA	Crown Vetch (seed crop)	
23021AA	Sainfoin	
23021BA	Sainfoin (seed crop)	
		General Information: If fall-treated legumes should be killed in winter, do not plant small grains or grass crops in the same field in the spring.
	0.5-2 (50% WP)	Broadcast. Apply to established legumes during fall or winter after the last cutting when temperatures are cool but before the ground freezes. Apply to fall-seeded legumes after the trifoliate stage. Application to spring-seeded legumes should be made the following fall or early winter.
	Birdsfoot Trefoil (seed crop)	See Birdsfoot Trefoil cluster.
01002AA	Blackberry	0.05 ppm Do not use more than 3 lb a.i./A per year.
01006AA	Raspberry	
	1-3 (50% WP)	Use limited to OR and WA., Broadcast or band. Apply to established berries, and make only 1 application per year. Apply in fall or winter, preferably during November or December. Do not apply when ground is frozen. Do not apply to newly transplanted berries for at least 3 months. Use 1 to 2 lb a.i./A for control of annual bluegrass, and 2 to 3 lb a.i./A for control of perennial ryegrass and quackgrass.
01009AA	Blueberry	0.05 ppm Do not use more than 2 lb a.i./A per year.
	1-2 (50% WP)	Use limited to OR and WA. Broadcast or band. Apply to established berries, and make only 1 application per year. Apply in fall or winter, preferably during November or December. Do not apply when ground is frozen. Do not apply to newly transplanted blueberries until the roots are well established.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Cherry	See Apple cluster.
	Clover	See Birdsfoot Trefoil cluster.
	Clover (seed crop)	See Birdsfoot Trefoil cluster.
	Crown Vetch	See Birdsfoot Trefoil cluster.
	Crown Vetch (seed crop)	See Birdsfoot Trefoil cluster.
13015AA 13020AA	Endive (Escarole) Lettuce	2 ppm (endive (escarole)) 1 ppm (lettuce) Fifty-five day preharvest interval on lettuce.
		General Information: Do not make more than 1 application per crop season. Do not use on peat or muck soils. Do not use more than 1.5 lb a.i./A on Val Temp, Grande Verde, and Prima Verde varieties of crisp lettuce, or on endive and escarole. Apply preemergence to the weeds, and water into the soil immediately after application.
	1.5-2 (50% WP)	Preplant soil incorporation. Broadcast or band. Where rainfall is not dependable or overhead spinkler irrigation is not used, shallow preplant incorporation followed by furrow irrigation is recommended.
	1-2 (50% WP)	Preplant or preemergence. Broadcast or band surface application.
	1-2 (50% WP)	Postemergence. Broadcast or band surface application. Apply before or after thinning of lettuce.
	Grapes	See Apple cluster.
	Lettuce	See Endive (Escarole) cluster.
	Nectarine	See Apple cluster.
	Peach	See Apple cluster.
	Pear	See Apple cluster.
	Plum	See Apple cluster.
	Prune	See Apple cluster.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Raspberry	See Blackberry cluster.
	Sainfoin	See Birdsfoot Trefoil cluster.
	Sainfoin (seed crop)	See Birdsfoot Trefoil cluster.
	TERRESTRIAL NON-FOOD CROP	
	(Agricultural Crops)	
33017BA	Bermudagrass (seed crop)	N.F. (seed) Do not graze treated areas or feed clippings to livestock.
	0.5-1.5 (50% WP)	Broadcast application for annual bluegrass control. Apply at any stage of annual bluegrass growth from preemergence to seed formation. Use the lower dosage for preemergence or early postemergence control. Use the higher dosage for late postemergence control and when longer preemergence residual control is desired. Irrigation or rainfall within 24 hours of application is desirable. May be applied by air.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	(Ornamental Plants and Forest Trees)	
/34022AA	Azalea	
/34022DA	Azalea (nursery stock)	
/30005AA	Christmas Tree Plantations	
/35044AA	Douglas-Fir	
/35044DA	Douglas-Fir (nursery stock)	
/35051AA	Fir	
/35051DA	Fir (nursery stock)	
/34062AA	Forsythia	
/34062DA	Forsythia (nursery stock)	
/34070AA	Holly	
/34070DA	Holly (nursery stock)	
/35073AA	Juniper	
/35073DA	Juniper (nursery stock)	
/35098AA	Pine	
/35098DA	Pine (nursery stock)	
/34118AA	Rhododendron	
/34118DA	Rhododendron (nursery stock)	
/35130AA	Yew	
/35130DA	Yew (nursery stock)	
	1-2 (50% WP)	Broadcast or band. Make a single application in fall prior to leaf-drop and before the soil freezes. Apply over the top of ornamentals or as a directed spray to the soil. Moisture is necessary as rainfall or overhead sprinkler irrigation to move the chemical into the soil. Use only on established plantings. Do not use on seedling trees or shrubs less than 1 year old, or on fall transplanted stock within 1 year of transplanting, or on spring transplanted stock within 6 months of transplanting.
	Azalea (nursery stock)	See Azalea cluster.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
33017AA	Bermudagrass	General Information: Use for control of annual bluegrass in bermudagrass golf courses, lawns, and playing fields. Do not spray on fairways or other areas that may drain onto bentgrass greens, or to areas overseeded with sensitive cool season grasses. Do not apply to areas that are to be overseeded with cool season grasses within 90 days before seeding. Do not use on golf greens. Dichondra, bluegrass, annual and perennial ryegrasses, fescues, zoysia, and bentgrass are sensitive to pre- and postemergence applications of pronamide. May be used for elimination of winter overseeded cool season grasses.
	0.92-2.75 oz a.i./ 5,000 sq.ft (1% G) (50% WP) 1.85-2.77 oz a.i./ 5,000 sq.ft (0.33% G)	Broadcast application for annual bluegrass control. Apply at any stage of annual bluegrass growth from preemergence to seed formation. Use the lower dosage for preemergence or early postemergence control. Use the higher dosage for late postemergence control and when longer residual preemergence control is desired. Irrigation or rainfall within 24 hours of application is desirable.
	0.92-2.75 oz a.i./ 5,000 sq.ft (50% WP)	Restricted Use Pattern. Applications should be made only by certified applicators or persons under their direct supervision. Broadcast application for annual bluegrass control. Apply at any stage of annual bluegrass growth from preemergence to seed formation. Use the lower dosage for preemergence or early postemergence control. Use the higher dosage for late postemergence control and when longer residual preemergence control is desired. Irrigation or rainfall within 24 hours of application is desirable.
	0.87 oz a.i./ 5,000 sq.ft (0.32% G) 0.85 oz a.i./ 5,000 sq.ft (0.4% G) 0.81 oz a.i./ 5,000 sq.ft (0.9% G)	Broadcast application for annual bluegrass control and for elimination of winter overseeded cool season grasses. For control of annual bluegrass, apply anytime after its germination in the fall through the spring. For elimination of winter overseeded cool season grasses and conversion to bermudagrass on golf greens and tees, apply in spring when the weather is favorable for bermudagrass growth.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Bermudagrass (continued)	
1.73 oz a.i./5,000 sq.ft (0.32% G)	Broadcast application for control of Kentucky bluegrass and bentgrass in areas other than golf greens and tees. Apply anytime when these grasses are actively growing.
1.7 oz a.i./5,000 sq.ft (0.4% G)	
1.62 oz a.i./5,000 sq.ft (0.9% G)	
Douglas-Fir	See Azalea cluster.
Douglas-Fir (nursery stock)	See Azalea cluster.
Fir	See Azalea cluster.
Fir (nursery stock)	See Azalea cluster.
Forsythia	See Azalea cluster.
Forsythia (nursery stock)	See Azalea cluster.
Holly	See Azalea cluster.
Holly (nursery stock)	See Azalea cluster.
Juniper	See Azalea cluster.
Juniper (nursery stock)	See Azalea cluster.
Pine	See Azalea cluster.
Pine (nursery stock)	See Azalea cluster.
Rhododendron	See Azalea cluster.
Rhododendron (nursery stock)	See Azalea cluster.
Yew	See Azalea cluster.
Yew (nursery stock)	See Azalea cluster.

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	FORESTRY	
	Christmas Tree Plantations	See TERRESTRIAL NON-FOOD CROP, Azalea cluster.
	AERIAL AND TANK MIX APPLICATIONS	
001500	Aerial Application	
AAAAAA	--	Refer to TERRESTRIAL NON-FOOD CROP (Agricultural Crops) Bermudagrass (seed crop)

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

Listing of Registered Pesticide Products by Formulation

050.0002 50% formulation intermediate
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
000707-00098

000.3204 0.32% granular
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
000538-00084

000.3304 0.33% granular
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
000557-01906

000.4004 0.4% granular
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
000538-00118

000.9004 0.9% granular
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
000538-00115

001.0004 1% granular
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
005481-00170

050.0006 50% wettable powder
3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide (101701)
000707-00159 002169-00248

999999 State Label Registrations

AZ Reg. No.
000707-07623

CA Reg. No.
000707-04595 005481-07509

FL Reg. No.
002342-06948

KS Reg. No.
000707-04594

NM Reg. No.
000707-06619

OR Reg. No.
000707-07620

WA Reg. No.
000707-04596

EPA Index to Pesticide Chemicals

3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL)BENZAMIDE

Appendix B

Listing of Registration Numbers by Site and Formulation

TERRESTRIAL FOOD CROP

(Agricultural Crops)

23001AA	Alfalfa (50% WP) 000707-00159
23001BA	Alfalfa (seed crop) (50% WP) 000707-00159
4001AA	Apple (50% WP) 000707-00159
13018AA	Artichoke, Globe (50% WP) 000707-00159
23011AA	Birdsfoot Trefoil (50% WP) 000707-00159
23011BA	Birdsfoot Trefoil (seed crop) (50% WP) 000707-00159
1002AA	Blackberry (50% WP) 000707-00159
1009AA	Blueberry (50% WP) 000707-00159
5002AA	Cherry (50% WP) 000707-00159
23003AA	Clover (50% WP) 000707-00159
23003BA	Clover (seed crop) (50% WP) 000707-00159

Appendix B

Listing of Registration Numbers by Site and Formulation (continued)

/23024AA	Crown Vetch	(50% WP)	000707-00159
/23024BA	Crown Vetch (seed crop)	(50% WP)	000707-00159
/13015AA	Endive (Escarole)	(50% WP)	000707-00159
/01014AA	Grapes	(50% WP)	000707-00159
/13020AA	Lettuce	(50% WP)	000707-00159
/05003AA	Nectarine	(50% WP)	000707-00159
/05004AA	Peach	(50% WP)	000707-00159
/04003AA	Pear	(50% WP)	000707-00159
/05005AA	Plum	(50% WP)	000707-00159
/05006AA	Prune	(50% WP)	000707-00159
/01006AA	Raspberry	(50% WP)	000707-00159
/23021AA	Sainfoin	(50% WP)	000707-00159

Listing of Registration Numbers by Site and Formulation (continued)

23021BA Sainfoin (seed crop)
(50% WP)
000707-00159

TERRESTRIAL NON-FOOD CROP

(Agricultural Crops)

33017BA Bermudagrass (seed crop)
(50% WP)
000707-00159

(Ornamental Plants and Forest Trees)

34022AA Azalea
(50% WP)
000707-00159

34022DA Azalea (nursery stock)
(50% WP)
000707-00159

33017AA Bermudagrass
(0.32% G)
000538-00084

(0.33% G)
000557-01906

(0.4% G)
000538-00118

(0.9% G)
000538-00115

(1% G)
005481-00170

(50% WP)
000707-00159 002169-00248

35044AA Douglas-Fir
(50% WP)
000707-00159

Listing of Registration Numbers by Site and Formulation (continued)

/35044DA Douglas-Fir (nursery stock)
(50% WP)
000707-00159

/35051AA Fir
(50% WP)
000707-00159

/35051DA Fir (nursery stock)
(50% WP)
000707-00159

34062AA Forsythia
(50% WP)
000707-00159

/34062DA Forsythia (nursery stock)
(50% WP)
000707-00159

/34070AA Holly
(50% WP)
000707-00159

/34070DA Holly (nursery stock)
(50% WP)
000707-00159

/35073AA Juniper
(50% WP)
000707-00159

/35073DA Juniper (nursery stock)
(50% WP)
000707-00159

/35098AA Pine
(50% WP)
000707-00159

/35098DA Pine (nursery stock)
(50% WP)
000707-00159

Appendix B

Listing of Registration Numbers by Site and Formulation (continued)

/34118AA	Rhododendron (50% WP) 000707-00159
/34118DA	Rhododendron (nursery stock) (50% WP) 000707-00159
35130AA	Yew (50% WP) 000707-00159
35130DA	Yew (nursery stock) (50% WP) 000707-00159
	FORESTRY
/30005AA	Christmas Tree Plantations (50% WP) 000707-00159

APPENDIX C

LABELING REQUIREMENTS

1. Submission of Revised Labeling
2. 40 CFR 162.10 Labeling Requirements
3. Table of Labeling Requirements
4. Physical/Chemical Hazards Labeling Statement
5. Pesticide Storage Instructions
6. Container Disposal Instructions
7. Farmworker Safety Label Requirements

APPENDIX C-1

SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (Appendix C-2) and are summarized for products containing this active ingredient in Appendix C-3. Applications submitted in response to this Standard must include draft labeling for Agency review.

If revised labeling information complying with this Appendix and the requirements described in Part II of the Standard, is not submitted, EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. LABEL CONTENTS. 40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix C-3.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound, 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - For products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "POISON" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "POISON." [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD -

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix C-4. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

   i. The flame extension is zero inches;

   ii. There is no flashback; and

   iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA section 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

The Agency has determined that certain formulations of pronamide are to be restricted. The Regulatory Position and Rationale states which products containing this active ingredient are classified for restricted use. The draft label(s) for these products submitted to the Agency as part of the application must reflect this determination (see below).

If a registrant does not believe that its product should be classified for restricted use, the registrant must submit any information and rationale with its application for reregistration. During the Agency's review of the application, the proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). The registrant will be notified of the Agency's classification decision.

1. For products classified for restricted use, the following label requirements apply:

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word. (40 CFR 162.10(h)(1)(iv))

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in the Standard). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. For products with some but not all uses restricted, if stated in the Regulatory Position and Rationale section, several courses of action are available:

   a. The product may be labeled for restricted use. The label may include uses that are unrestricted, but they may not be distinguished on the label as being unrestricted.

   b. All restricted uses may be deleted from the label (submit draft labeling bearing only unrestricted uses).

   c. Two separate products with identical formulations, one bearing only unrestricted uses and the other bearing restricted uses, may be registered. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. The products will be assigned separate registration numbers.

Item 9B - There is no Item 9B.

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - A reentry interval has not been established by the Agency for this chemical.

Item 10B - There is no Item 10B.

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Part II of the Standard contains the specific disposal statement for pronamide and Appendix C-6 sets forth the appropriate container disposal statements.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

B. COLLATERAL LABELING. Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this Standard and submitted for review.

Chapter 1--Environmental Protection Agency

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(3) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

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(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

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(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 30°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

APPENDIX C-3 - TABLE OF LABELING REQUIREMENTS

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

APPENDIX C-4

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

APPENDIX C-5

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading: All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions: All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop its own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

APPENDIX C-6

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

APPENDIX C-7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 29 1983

PR NOTICE 83-2

NOTICE TO MANUFACTURERS, FORMULATORS AND REGISTRANTS OF PESTICIDES

Attention: Persons Responsible for Federal Registrations of Pesticides

This notice is to inform you that the labels of all outdoor agricultural use products which are applied to crops whose culture requires hand labor are required to bear the following information under the Farmworker Safety Label Improvement Program. No application for amended registration is required, provided you use the exact wording contained in this Notice. All affected products released for shipment after December 31, 1984 must be relabeled accordingly.

For the purposes of this Label Improvement Program, the terms "reentry intervals", "farmworkers", and "protective clothing" used in this notice are as defined in 40 CFR 170.2. Reentry interval means the period of time immediately following the application of a pesticide to a field when unprotected workers should not enter. Farmworker refers to any person or persons engaged in agricultural hand labor in the field. Protective clothing means, at least, a hat or other suitable head covering, a long sleeved shirt and long legged trousers or a coverall type garment (all of closely woven fabric covering the body, including the arms and legs), shoes and socks.

The term hand labor tasks, as used in this Notice, is defined as commonly recognized crop production activities such as harvesting, detasselling, thinning, weeding, topping, planting, sucker removal, summer pruning, moving irrigation equipment and other hand labor tasks performed in the field by farmworkers who will come in substantial contact with pesticide treated surfaces, such as plants or plant parts. For the purposes of this notice, mixing, loading, flagging, and equipment operation are considered to be part of the application of the pesticide and are not normally considered to be hand crop production tasks, and therefore, are not subject to these provisions. At a minimum, the following crops have been determined to employ hand labor tasks:

Citrus Fruit
Cucurbits
Fruiting Vegetables
Leafy Vegetables
Root Crop Vegetables
Onions
Pome Fruits
Stone Fruits
Tobacco
Small Fruits (berries, grapes, nuts)
Corn (hybrid seed, sweet and pop)
Figs
Mango
Olives
Pineapples

Registrants are responsible for determining whether use of their products would involve any other crop activities that meet the definition for hand labor tasks normally performed by farmworkers and are, thus, subject to this Notice.

While "scouting" for determining efficacy may result in potential exposure, it is not considered to be a commonly recognized hand labor crop production task customarily performed by farmworkers and therefore would normally be excluded from the hand labor criteria of this Notice. However, if the definition of hand labor would cover scouting for a particular use, then these provisions would apply.

I. PRODUCTS AFFECTED:

All products with outdoor agricultural uses which are applied to crops utilizing hand labor tasks will be required to bear general precautionary label language about farmworker safety (see Section II.A.) In addition, the labels of the following pesticides, either as sole active ingredients or in combination with other pesticides, must bear specific precautionary label language about reentry and farmworker safety (see Section II. A. and B.).

Ethyl Parathion
Methyl Parathion
Azinphos Methyl
Demeton
Monocrotophos
Phosalone
Carbophenothion
Endrin
Metasystox-R
Bidrin
Ethion

The requirements set forth in this Notice do not apply to: (1) Mosquito abatement treatments and related public pest control programs; (2) Greenhouse treatments; (3) Livestock and other animal treatments; (4) Treatment of golf courses, forest uses and similar nonagricultural areas; (5) Any uses, except pesticides with systemic modes of action, for which soil incorporation is required.

The reentry intervals for the eleven pesticides listed above and EPN were established through regulation at 40 CFR 170. EPN was excluded from this label improvement action because an RPAR is currently under negotiation. Registrants will be notified separately of requirements resulting from the RPAR action.

EPA, as part of the reregistration process, is evaluating the reentry intervals and protective clothing requirements for all pesticides including the ones addressed in this label improvement program. Registrants will be advised through the Registration Standards Program if future label changes are necessary.

II. REQUIRED LABEL CHANGES:

The following statements contain either the exact wording that must appear on the affected product labels, or are explicit in indicating the type of information that must be conveyed in specific portions of the label text. See attached sample product label for proper placement of each statement listed in this Section (A and B).

A. General Worker Protection Statements:

The labels of all products covered by this notice must bear the following general precautionary statements about farmworker safety. See the sample label provided in attachment B for the proper location for these statements.

1. "Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons."

2. "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

3. The labels of all products in Toxicity Category I and II, in addition to the English signal word, must include the Spanish language equivalent on the front panel. The appropriate Spanish signal word, "PELIGRO" (for DANGER) or "AVISO" (for WARNING) must appear in capital letters of the same type size as the equivalent English signal word.

4. Agricultural products in Toxicity Category I and II must bear minimum Spanish language precautionary statements. The following precautionary statement must be placed on the label in proximity to the Spanish signal word:

   "PRECAUCION AL USUARIO: Si usted no lee ingles, no use este producto hasta que le etiqueta haya sido explicado ampliamente".

   (TRANSLATION: TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you. The English translation of the Spanish precautionary statement is not required to appear on your product label.)

5. All agricultural use products applied to crops utilizing hand labor tasks, except as specified in Section B (1) of this Notice, must bear the following label statement:

   "Do not enter treated areas without protective clothing until sprays have dried (or, if appropriate, dusts have settled)."

6. "Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information."

7. "Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. (Indicate specific oral warnings which inform workers of areas or fields that may not be entered without specific protective clothing, period of time field must be vacated and appropriate actions to take in case of accidental exposure.) When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written warnings must include the following information: '(Appropriate signal word DANGER or WARNING). Area treated with (name of pesticide) on (date of application). Do not enter without appropriate protective clothing for (insert here reentry interval for your product). (insert here actions to take in case of accidental exposure.)'" This statement may either appear on the label (see Attachment B for specific location) or on the labeling accompanying the product.

B. Specific Reentry and Farmworker Safety Statements:

Because of their inherent human toxicity and to reduce risks for crop use patterns utilizing hand labor, the Agency has determined that all products with reentry intervals established through 40 CFR 170 must bear the following label statement:

> "Do not enter treated areas for (insert here appropriate reentry time interval from chart below) hours unless appropriate protective clothing is worn."

Reentry Intervals

Ethyl Parathion	48 hrs.	Monocrotophos	48 hrs.	Demeton	48 hrs.
Metasystox-R	48 hrs.	Phosalone	24 hrs.	Bidrin	48 hrs.
Methyl Parathion	48 hrs.	Carbophenothion	48 hrs.	Ethion	24 hrs.
Azinphos Methyl	24 hrs.	Endrin	48 hrs.		

III. Compliance:

It is the responsibility of the registrants to ensure that the labels of their products, including distributor products, contain specific instructions pertaining to farmworker safety. Existing stocks of products in channels of trade (that is, out of the registrant's physical possession) prior to December 31, 1984, need not be relabeled. All products released for shipment after December 31, 1984, must meet the requirements of this Notice, or they will be deemed misbranded under Section 2(q)(1)(G). Failure to revise product labeling in accordance with this Notice may also result in the initiation of cancellation proceedings.

If you wish to make changes not specified in this Notice, or to modify any of the required statements, you must submit an application for amended registration to the address listed below:

(Product Manager for your product listed in Attachment A)
Registration Division (TS-767-C)
U.S. Environmental Protection Agency

IV. Further Information:

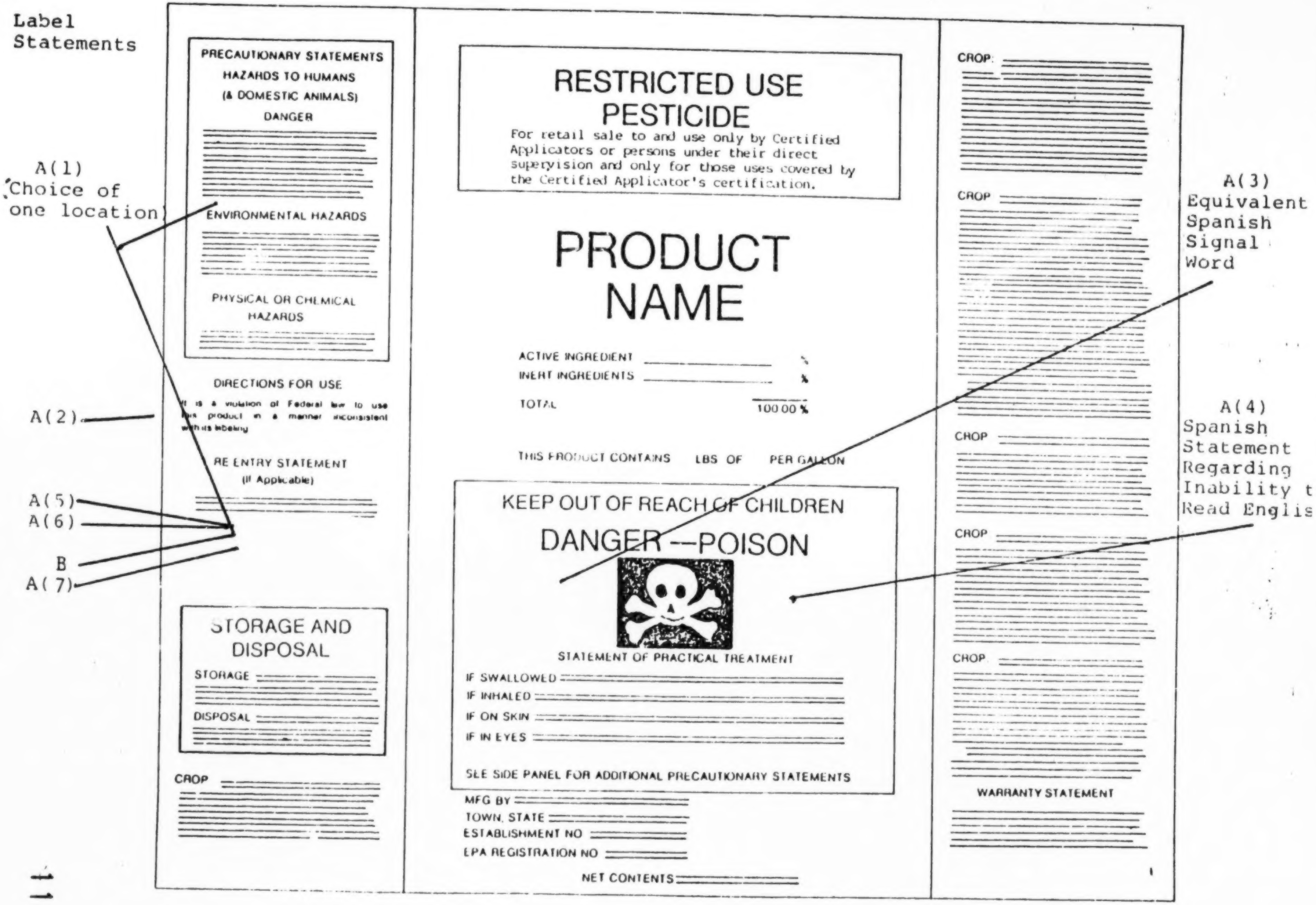
Questions on this Notice may be directed to the appropriate Product Manager or Richard King, Policy & Liaison Staff, Registration Division, at (703) 557-0592.

Douglas D. Campt, Director
Registration Division (TS-767-C)

Attachments

A. Product Manager Assignments (Attachment A not included)
B. Sample Product Label

ATTACHMENT B - Sample Label


Label Statements
A(1) Choice of one location
A(2)
A(5)
A(6)
B
A(7)
A(3) Equivalent Spanish Signal Word
A(4) Spanish Statement Regarding Inability t Read Englis
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
RE ENTRY STATEMENT
(If Applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP
RESTRICTED USE PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.
PRODUCT NAME
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00 %
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
DANGER --POISON
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

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APPENDIX D

FIFRA §3(c)(2)(B) Summary Sheet
(EPA Form 8580-1)

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO.**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

APPENDIX E

Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
(EPA Form 8580-6)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-8 (10-82)

APPENDIX F

Product Specific Data Report
(EPA Form 8540-1)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.______________ Guidance Document for________________________

Date________________________

Registration Guideline No.	Name of Test	Test not required for product listed above (check below)	Method of complying with data requirements		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for product listed above (check below)	Method of complying with data requirements		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX G

Formulator's Exemption Statement

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ______________________

Applicant's Name and Address ____

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ________________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ________________________________

Date ________________ Title ________________________________

EPA Form (April 1985)

BIBLIOGRAPHY

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Number). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A;

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
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MRID CITATION

00028772 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1973) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. Rev. By Univ. of California--Riverside, Dept. of Entomology. Riverside, Calif.: UC, Agricultural Extension Service. (Also in unpublished submission received Apr 2, 1980 under 464-556; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242149-Z)

00033380 Lodge, M.D.; Santelmann, P.W.; Lawrence, S.C.; et al. (1972) Analytical Results of Kerb Residue: R.A.R. No. 2-71-128. (Unpublished study including R.A.R. nos. 2-70-71, 2-70-86, 2-70-78..., received Dec 20, 1972 under 3F1317; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:092251-A)

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00125382	Rohm & Haas Co. (1982) Kerb 50-W Herbicide Use on Artichokes. (Compilation; unpublished study received Feb 4, 1983 under 707-159; CDL:249475-A)
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00133112	Powers, M. (1970) Acute Oral--Rats/Draize Eye--Rabbits/Acute Dermal--Rabbits/Primary Skin--Rabbits/Acute Inhalation Exposure--Rats: Kerb 50-W. Final rept. (Unpublished study received Feb 25, 1971 under 707-98; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:004358-A)
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